

EPA United States Environmental Protection Agency Washington, DC 20460 Work Assignment						Work Assignment Number 3-03	
						<input type="checkbox"/> Other <input type="checkbox"/> Amendment Number:	
Contract Number EP-C-11-005			Contract Period 01/01/2011 To 12/31/2014			Title of Work Assignment/SF Site Name	
			Base Option Period Number 3			Incorporation of New Technolog	
Contractor ICF INCORPORATED, L.L.C.				Specify Section and paragraph of Contract SOW 3.1, 3.3, 3.4, 3.6			
Purpose: <input checked="" type="checkbox"/> Work Assignment <input type="checkbox"/> Work Assignment Close-Out <input type="checkbox"/> Work Assignment Amendment <input type="checkbox"/> Incremental Funding <input type="checkbox"/> Work Plan Approval						Period of Performance From 01/01/2014 To 12/31/2014	
Comments:							
<input type="checkbox"/> Superfund Accounting and Appropriations Data <input checked="" type="checkbox"/> Non-Superfund							
SFO (Max 2) <input type="checkbox"/> Note: To report additional accounting and appropriations date use EPA Form 1900-69A.							
Line	DCN (Max 6)	Budget/FY (Max 4)	Appropriation Code (Max 6)	Budget Org/Code (Max 7)	Program Element (Max 9)	Object Class (Max 4)	Amount (Dollars) (Cents) Site/Project (Max 8) Cost Org/Code (Max 7)
1							
2							
3							
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5							
Authorized Work Assignment Ceiling							
Contract Period:		Cost/Fee:		LOE:			
01/01/2011 To 12/31/2014							
This Action:							
Total:							
Work Plan / Cost Estimate Approvals							
Contractor WP Dated:				Cost/Fee:		LOE:	
Cumulative Approved:				Cost/Fee:		LOE:	
Work Assignment Manager Name Shamima Akhter						Branch/Mail Code:	
_____ (Signature) (Date)						Phone Number 202-566-0000	
						FAX Number:	
Project Officer Name Shirley Harrison						Branch/Mail Code:	
_____ (Signature) (Date)						Phone Number: 202-566-1107	
						FAX Number:	
Other Agency Official Name Shirley Harrison						Branch/Mail Code:	
_____ (Signature) (Date)						Phone Number: 202-566-1107	
						FAX Number:	
Contracting Official Name Sandra Stargardt-Licis						Branch/Mail Code:	
_____ (Signature) (Date)						Phone Number: 513-487-2006	
						FAX Number:	

**PERFORMANCE WORK STATEMENT
ICF CONTRACT EP-C-11-005
WORK ASSIGNMENT # 3-03**

Title: Incorporation of New Technologies to Support Criteria Development and Implementation

Work Assignment Manager: Shamima Akhter
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Alternate WAM: John Ravenscroft
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Washington, DC 20460
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E-mail: ravenscroft.john@epa.gov

Period of Performance: January 1, 2014 through December 31, 2014

Contractor SOW: 3.1, 3.3, 3.4, 3.6

Background:

An important goal of the Clean Water Act (CWA) is to protect and restore waters for swimming. A key component in the CWA framework for protecting and restoring waters for swimming is State adoption of water Quality Standards (WQS) to protect swimmers from illnesses associated with "microbes" in the water. One of the EPA's key roles is to recommend recreational water quality criteria (under section 304(a) of the CWA) for adoption by the States. These EPA recommended criteria have been historically based on fecal matter in the water; in the 1960's the Federal Government recommended certain levels of fecal coliform as the recreational criteria and in 1986 EPA recommended certain enterococci and E. coli as its new recreational criteria.

In order to continue to provide increased protection to swimmers and for development of Total Maximum Daily Loads (TMDLs), National Pollutant Discharge Elimination System (NPDES) permitting requirements and water quality listings, EPA is now poised to revise its ambient water quality criteria. The old criteria developed in 1986 was mainly based on enumerations of Fecal Indicator Bacteria (FIB) using culture-based methods, some of which were originally developed over a century ago. The advent of scientific methods particularly in the molecular measurements of diverse microbial populations, analytical chemistry, virology, genomics including metagenomics warrant reevaluations of the 1986 criteria development process. Research advances have revealed many of the shortcomings and uncertainties associated with the 1986

water quality criteria. EPA is committed to develop new recreational water quality criteria for all water body types by 2012. Before new criteria can be developed, it is imperative that EPA undertakes critical research, analyze existing research data so that a scientifically defensible and health protective criteria can be adopted.

New molecular assays with intrinsic characteristics of high sensitivity, specificity, and reproducibility allow more direct enumeration of potential pathogens in recreational water. For example, Immunomagnetic Separation / Adenosine Triphosphate (IMS/ATP), TaqMan Protein Assays, fluorescent-based microbe detection assays allow enumerations of indicator organisms very reliably. EPA is contemplating inclusion of Quantitative Polymerase Chain reaction (qPCR) based enumerations of FIBs that can rapidly produce actionable results as opposed to the 24-48 hours that is now needed for culture based laboratory analysis. However, before new technologies can be incorporated in criteria development, numerous regulatory hurdles and related research needs must be met.

EPA anticipates a need to find out how we can use the data from the new technologies in the criteria development in the absence of epidemiological studies.

Quality Assurance:

The tasks in this Performance Work Statement (PWS) require the use of secondary data/analyses and fall under the scope of the approved contract-level QAPP. Consistent with the Agency's quality assurance (QA) requirements, the contractor must assure the quality and analyses of the secondary data and other data collected to be used under this work assignment.

The Contractor shall discuss with the EPA WAM if any of the specific work assignment tasks are not readily covered under the approved QAPP. Any additional quality assurance requirements must be addressed in the work plan and monthly progress reports and, if needed, be covered by a work assignment-specific QAPP supplement, which must be approved by the EPA WAM before activities covered by the additional QA language begin under this work assignment.

PERFORMANCE WORK STATEMENT (PWS):

Task 1: Work plan and monthly progress reports

The contractor shall develop a detail work plan and cost estimate for each task outlined in this work assignment. The plan should contain, but not limited to, work-flowchart, elaborate schedule (task-wise), staffing plan and qualifications of proposed staff, budget for each task and level of effort (LOE). Prior to the submission of the work plan, the contractor shall consult with the EPA WAM via conference call to mitigate any potential issues that need clarifications. The contractor shall include information on plans to manage work and control contract costs. All P levels, hours and total dollars for each task will be provided and costs greater than \$100.00 shall be itemized in detail. The contractor shall provide their job number with all invoices to facilitate their expediency. The plan should be submitted no later than fifteen (15) working days after receiving this work assignment.

This task also includes monthly progress and financial reports. The monthly progress report shall indicate, in a separate QA section, whether significant QA issues have been identified and how they are being resolved. Monthly financial reports must include a table with the invoice LOE and costs' broken out by the tasks in this work assignment.

Task 1.2: Information Quality Guidelines

The Contractor shall ensure the products developed under this work assignment comply with the EPA Information Quality Guidelines and shall complete the Checklist for Influential Information as needed for each deliverable from this work assignment as they may be used in Agency decision-making and/or will be publicly available documents. The EPA WAM will provide the checklist to the Contractor. The Contractor shall provide a memorandum describing how the planned product(s) developed meet EPA's Information Quality Guidelines checklist. As part of that memo, the Contractor shall document the quality assurance procedures it used in developing the deliverables under this PWS. The Contractor shall provide the memo at the time it delivers the Final Summary Report. The Contractor shall have a teleconference with the EPA WAM to discuss the Guidelines and the Contractor's role in completing the checklist.

Task 4: Develop Technical Support Documents

In order to develop Technical Support Documents for criteria implementation, EPA is anticipating detailed analyses of Task 2 (previous WA 2-03) that shall be the basis of completing Task 4. This work shall provide a tool for states to develop new methods or indicators for their water quality standards on a site-specific basis. Information on demonstrating the relationship between two-indicator method combinations shall be characterized under this task. The contractor shall be aware of the following time-line to generate the deliverable. The deliverable will go for internal/management review followed by the external peer review. Afterwards, the peer reviewed deliverable will again be evaluated by internal/management team.

- | | |
|---|---------------------------|
| • Management review - | Nov19 – Dec 19, 2013 |
| • Conduct peer review | January 20, 2014 |
| • Final Peer Review Report - | March 10, 2014 |
| • Response to peer review comments – | March 11 – April 10, 2014 |
| And incorporation of any changes to the deliverable (ICF) | |

After Peer Review

- | | |
|--------------------------|---------------------|
| • Internal Review HECD - | April 11 – 25, 2014 |
| • Management review - | May 12 - 30, 2014 |
| • Final deliverable - | June 2014 |

Period of Performance/Milestones: It is the Contractor's responsibility to coordinate with EPA WAM while conducting these tasks.

Task	Milestone	Date due
1	Work Plan	Due 15 calendar days after receipt of WA
1	1.1 QAPP	Within 3 weeks of receipt of WA
1	Kick-off meeting with EPA WAM	1 week after WP approval
4	Draft Report	2 months after WP approval
4	Revised Report	June 2014

Knowledge and Skills Required: Contractor shall have expertise in preparing the aforementioned materials and be knowledgeable with the various fields of discipline discussed in this work assignment. The Contractor shall have practical experience in statistical methods and have analysis and have advanced credentials in environmental microbiology. The contractor shall be familiar with the use of fecal indicator organisms, microbiological analytical methods (including molecular techniques) water monitoring, applications of epidemiological data, determination of human exposure to environmental contaminant sources, and gastrointestinal disease endpoints, and other factors associated with needs in recreational water quality and CWA 304(a) criteria development.

General Requirements of the Work Assignment and Schedule:

Due Dates: The Contractor shall provide due dates that are mutually acceptable with the EPA WAM. The Contractor shall notify the EPA WAM in advance, if a due date will not be met and request a revised date.

Delays: The Contractor shall make every effort to ensure there are no Contractor-caused delays. If a delay is inevitable, it is the Contractor's responsibility to notify the EPA WAM at the first sign of said delay. A revised schedule will then be worked out.

Draft Documents: The Contractor may be required to submit draft documents. Draft documents shall be prepared in an electronic format compatible with current Microsoft products. EPA WAM will provide comments on draft submissions prior to submission of final documents.

Final Documents: The Contractor shall submit final documents both electronically and in hardcopy to EPA WAM.

Final Documents: The Contractor shall revise and incorporate all EPA's comments and submit final documents both electronically and in hardcopy (Microsoft version 2003 or higher) to EPA WAM. The Agency may decide to publish the report on the web. If this occurs, the report will need to be 508 compliant and the COR will provide appropriate technical direction.

Final Peer Reviewed Document: Upon receipt of the EPA's external expert peer-review of the Contractor's Final Written Report, the EPA WAM will provide the Contractor with the recommended edits and modifications. The Contractor shall address all recommended peer-review modifications. Changes will be documented in a separate report for the record to describe

how the peer-review comments were incorporated into the final report. The Contractor shall provide the revised final report (and documented changes to the report) to the EPA WAM for review. Upon the EPA WAM's approval, the Contractor shall send the final revised peer-reviewed report in Microsoft Word, version 2003 or higher, to the EPA WAM.

MEETINGS, CONFERENCES, TRAINING EVENTS, AWARD CEREMONIES AND RECEPTIONS:

All appropriate clearances and approvals required by Agency policy in support of any and all conference related activities and expenses, including support of meetings, conferences, training events, award ceremonies and receptions, shall be obtained by the EPA PO as needed and provided to the Contracting Officer. Work under conference related activities and expenses shall not occur until this approval is obtained and provided by the EPA PO.

EPAUnited States Environmental Protection Agency
Washington, DC 20460**Work Assignment**

Work Assignment Number

3-03

☐ Other ☒ Amendment Number:
000001

Contract Number

EP-C-11-005

Contract Period 01/01/2011 To 12/31/2014

Base ☒ Option Period Number

Title of Work Assignment/SF Site Name

Incorporation of New Technolog

Contractor

ICF Incorporated, L.L.C.

Specify Section and paragraph of Contract SOW

3.1, 3.3, 3.4, 3.6

Purpose:

☐

Work Assignment

☐

Work Assignment Close-Out

☒

Work Assignment Amendment

☐

Incremental Funding

☐

Work Plan Approval

Period of Performance

From 01/01/2014 To 12/31/2014

Comments:

☐

Superfund

Accounting and Appropriations Data

☒

Non-Superfund

SFO
(Max 2)☐

Note: To report additional accounting and appropriations data use EPA Form 1900-69A.

Line	DCN (Max 6)	Budget/FY (Max 4)	Appropriation Code (Max 6)	Budget Org/Code (Max 7)	Program Element (Max 9)	Object Class (Max 4)	Amount (Dollars)	(Cents)	Site/Project (Max 8)	Cost Org/Code (Max 7)
1										
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4										
5										

Authorized Work Assignment Ceiling

Contract Period:

01/01/2011 To 12/31/2014

Cost/Fee:

LOE:

This Action:

Total:

Work Plan / Cost Estimate Approvals

Contractor WP Dated:

Cost/Fee:

LOE:

Cumulative Approved:

Cost/Fee:

LOE:

Work Assignment Manager Name Shamima Akhter

Branch/Mail Code:

Phone Number 202-566-0000

FAX Number:

(Signature)

(Date)

Project Officer Name Shirley Harrison

Branch/Mail Code:

Phone Number: 202-566-1107

FAX Number:

(Signature)

(Date)

Other Agency Official Name Shirley Harrison

Branch/Mail Code:

Phone Number: 202-566-1107

FAX Number:

(Signature)

(Date)

Contracting Official Name Sandra Stargardt-Licis

Branch/Mail Code:

Phone Number: 513-487-2006

FAX Number:

(Signature)

(Date)

**PERFORMANCE WORK STATEMENT
ICF CONTRACT EP-C-11-005
WORK ASSIGNMENT # 3-03 Amendment 1**

Title: Incorporation of New Technologies to Support Criteria Development and Implementation

Work Assignment Contracting Shamima Akhter

Officer Representative (WACOR): Health and Ecological Criteria Division (Mail Code 4304T)
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U.S. Environmental Protection Agency
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Phone (202) 566-1341
E-mail: akhter.shamima@epa.gov

Alternate WACOR:

John Ravenscroft
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1200 Pennsylvania Ave, N.W.
Washington, DC 20460
Phone (202) 566-1101
E-mail: ravenscroft.john@epa.gov

Period of Performance: Work Assignment Amendment Issuance through December 31, 2014

Contractor SOW: 3.1, 3.3, 3.4, 3.6

Purpose of Amendment: The purpose of this amendment is to provide additional LOE and funding for Tasks 1 and 4. Deliverables under Task have necessitated additional rounds of review and editing that were not anticipated when the original work assignment was prepared. The additional LOE and funding will help to prepare useful deliverables of sufficient quality for EPA and maintain project timelines. Additional resources are also being provided for Task 1 for the remainder of the period of performance. Unless specifically mentioned, the language contained in the original work assignment still applies (e.g., Information Quality Guidelines, QA section, etc.). All deliverables remain unchanged. The contractor shall submit a cost estimate for this amendment.

The remaining milestones for Task 4 (Develop Technical Support Documents) are as follows:

- The contractor shall provide support in responding to comments from the independent peer review of the TSM document.
- The contractor shall incorporate comments and edits received from the WACOR, from both the peer review and the final round of internal management review.
- The contractor shall ensure the TSM document is fully prepared for publication on EPA's website once EPA comment approval is received.

EPA United States Environmental Protection Agency Washington, DC 20460 Work Assignment		Work Assignment Number 3-03								
		<input type="checkbox"/> Other <input checked="" type="checkbox"/> Amendment Number: 000002								
Contract Number EP-C-11-005	Contract Period 01/01/2011 To 12/31/2015 Base Option Period Number 3	Title of Work Assignment/SF Site Name Incorporation of New Technolog								
Contractor ICF INCORPORATED, L.L.C.		Specify Section and paragraph of Contract SOW								
Purpose: <input type="checkbox"/> Work Assignment <input type="checkbox"/> Work Assignment Close-Out <input checked="" type="checkbox"/> Work Assignment Amendment <input type="checkbox"/> Incremental Funding <input type="checkbox"/> Work Plan Approval		Period of Performance From 01/01/2014 To 12/31/2014								
Comments:										
<input type="checkbox"/> Superfund Accounting and Appropriations Data <input checked="" type="checkbox"/> Non-Superfund										
SFO (Max 2) <input type="checkbox"/> Note: To report additional accounting and appropriations date use EPA Form 1900-69A.										
Line	DCN (Max 6)	Budget/FY (Max 4)	Appropriation Code (Max 6)	Budget Org/Code (Max 7)	Program Element (Max 9)	Object Class (Max 4)	Amount (Dollars)	(Cents)	Site/Project (Max 8)	Cost Org/Code (Max 7)
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Authorized Work Assignment Ceiling										
Contract Period: 01/01/2011 To 12/31/2015		Cost/Fee:				LOE:				
This Action:										
Total:										
Work Plan / Cost Estimate Approvals										
Contractor W/P Dated:		Cost/Fee:				LOE:				
Cumulative Approved:		Cost/Fee:				LOE:				
Work Assignment Manager Name Shamima Akhter <div style="display: flex; justify-content: space-between;"> <div>_____ (Signature)</div> <div>_____ (Date)</div> </div>						Branch/Mail Code: Phone Number 202-566-0000 FAX Number:				
Project Officer Name Shirley Harrison <div style="display: flex; justify-content: space-between;"> <div>_____ (Signature)</div> <div>_____ (Date)</div> </div>						Branch/Mail Code: Phone Number: 202-566-1107 FAX Number:				
Other Agency Official Name Shirley Harrison <div style="display: flex; justify-content: space-between;"> <div>_____ (Signature)</div> <div>_____ (Date)</div> </div>						Branch/Mail Code: Phone Number: 202-566-1107 FAX Number:				
Contracting Official Name Sandra Stargardt-Licis <div style="display: flex; justify-content: space-between;"> <div>_____ (Signature)</div> <div>_____ (Date)</div> </div>						Branch/Mail Code: Phone Number: 513-487-2006 FAX Number:				

**PERFORMANCE WORK STATEMENT
ICF CONTRACT EP-C-11-005
WORK ASSIGNMENT # 3-03 Amendment 2**

Title: Incorporation of New Technologies to Support Criteria Development and Implementation

Work Assignment Contracting Shamima Akhter

Officer Representative (WACOR): Health and Ecological Criteria Division (Mail Code 4304T)
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Alternate WACOR:

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E-mail: ravenscroft.john@epa.gov

Period of Performance: WA Amendment Issuance through December 31, 2014

Purpose of Amendment: The purpose of this amendment is to provide additional LOE for Tasks 1 and 4. Deliverables under Task have necessitated reanalysis based on peer review comments, additional rounds of review and editing that were not anticipated when the amendment 1 was prepared. The additional LOE will help to prepare useful deliverables of sufficient quality for EPA and maintain project timelines. Additional resources are also being provided for Task 1 for the remainder of the period of performance. Unless specifically mentioned, the language contained in the original work assignment still applies (e.g., Information Quality Guidelines, QA section, etc.). All deliverables remain unchanged. The contractor shall submit a cost estimate for amendment 2.

The remaining milestones for Task 4 (Develop Technical Support Documents) are as follows:

- The contractor shall provide support in responding to comments from the independent peer review of the TSM document.
- The contractor shall incorporate comments and edits received from the WACOR, from both the peer review and the final round of internal management review.
- The contractor shall ensure the TSM document is fully prepared for publication on EPA's website once EPA comment approval is received.

EPA United States Environmental Protection Agency Washington, DC 20460 Work Assignment		Work Assignment Number 3-04 <input type="checkbox"/> Other <input type="checkbox"/> Amendment Number:								
Contract Number EP-C-11-005	Contract Period 01/01/2011 To 12/31/2014 Base Option Period Number 3	Title of Work Assignment/SF Site Name QMRA Activities to Support Cri								
Contractor ICF INCORPORATED, L.L.C.		Specify Section and paragraph of Contract SOW 3.1, 3.3, 3.6								
Purpose: <input checked="" type="checkbox"/> Work Assignment <input type="checkbox"/> Work Assignment Close-Out <input type="checkbox"/> Work Assignment Amendment <input type="checkbox"/> Incremental Funding <input type="checkbox"/> Work Plan Approval		Period of Performance From 01/01/2011 To 12/31/2014								
Comments:										
<input type="checkbox"/> Superfund Accounting and Appropriations Data <input checked="" type="checkbox"/> Non-Superfund										
SFO (Max 2) <input type="checkbox"/> Note: To report additional accounting and appropriations date use EPA Form 1900-69A.										
Line	DCN (Max 6)	Budget/FY (Max 4)	Appropriation Code (Max 6)	Budget Org/Code (Max 7)	Program Element (Max 9)	Object Class (Max 4)	Amount (Dollars)	(Cents)	Site/Project (Max 8)	Cost Org/Code (Max 7)
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4										
5										
Authorized Work Assignment Ceiling										
Contract Period: 01/01/2011 To 12/31/2014		Cost/Fee:				LOE:				
This Action:										
Total:										
Work Plan / Cost Estimate Approvals										
Contractor WP Dated:		Cost/Fee:				LOE:				
Cumulative Approved:		Cost/Fee:				LOE:				
Work Assignment Manager Name John Ravenscroft _____ (Signature) (Date)						Branch/Mail Code: Phone Number 202-566-1101 FAX Number:				
Project Officer Name Shirley Harrison _____ (Signature) (Date)						Branch/Mail Code: Phone Number: 202-566-1107 FAX Number:				
Other Agency Official Name Shirley Harrison _____ (Signature) (Date)						Branch/Mail Code: Phone Number: 202-566-1107 FAX Number:				
Contracting Official Name Sandra Stargardt-Licis _____ (Signature) (Date)						Branch/Mail Code: Phone Number: 513-487-2006 FAX Number:				

**Performance Work Statement
ICF Contract # EP-C-11-005
Work Assignment #3-04 (Carryover)**

Title: QMRA Activities to Support Criteria Development and Implementation

Work Assignment Manager: John Ravenscroft (Mail Code 4304T)
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Alternate WAM: Sharon Nappier (Mail Code 4304T)
Office of Water, Office of Science and Technology
Health and Ecological Criteria Division
1200 Pennsylvania Ave, N.W.
Washington, DC 20460
Telephone #: 202-566-0740
E-mail: nappier.sharon@epa.gov

Period of Performance: January 1, 2014 through December 31, 2014

****Note:** No CBI data will be needed in the course of this work assignment.

Contractor PWS: 3.1, 3.3, 3.6

Background: EPA is issued new CWA 304(a) Recreational Ambient Water Quality Criteria (AWQC) in December 2012. The science underpinning the new criteria describes human health effects and water quality studies conducted in waters impacted primarily by human sources of fecal contamination. EPA would like to better understand the risks associated with other fecal sources and the potential wet weather impacts on surface waters. Quantitative Microbial Risk Assessment (QMRA) has been identified as a tool that the Agency can use to complement existing health data and to better understand the relative risks associated with non-human fecal sources of surface water contamination. The Agency's previously supported QMRA efforts have indicated that there are potentially significant differences in health risks associated with different sources of fecal contamination and additional efforts are needed to better inform the regulatory framework. This work assignment covers various aspects of further development and application of QMRA in support of Recreational AWQC development and implementation.

Quality Assurance: The tasks in this Performance Work Statement (PWS) require the use of secondary data/analyses and fall under the scope of the approved contract-level QAPP. Consistent with the Agency's quality assurance (QA) requirements, the contractor must assure the quality and analyses of the secondary data and other data collected to be used under this PWS.

The Contractor shall discuss with the EPA WAM if any of the specific work assignment tasks are not readily covered under the approved QAPP. Any additional quality assurance requirements must be addressed in the work plan and monthly progress reports and, if needed, be covered by a WA-specific QAPP supplement, which must be approved by the EPA before activities covered by the additional QA language begin under this PWS.

Performance Work Statement (PWS): The scope in this PWS will fall under the following task areas:

Task 1: Work plan, monthly progress reports and quality assurance

Task 1.1: Work plan

The contractor shall develop a work plan to address all tasks in this work assignment. The work plan shall include a schedule, staffing plan, level of effort (LOE), and cost estimate for each task, the contractor's key assumptions on which staffing plan and budget are based, and qualifications of proposed staff. If a subcontractor(s) is proposed and subcontractors are outside the metropolitan DC area, the contractor shall include information on plans to manage work and contract costs. All P levels, hours and total dollars for each task will be provided and costs greater than \$100.00 shall be itemized in detail. The contractor shall provide their job number with all invoices to facilitate their expediency.

This task also includes monthly progress and financial reports. The monthly progress report shall indicate in a separate QA section, whether significant QA issues have been identified and how they are being resolved. Monthly financial reports must include a table with the invoice LOE and costs delineated by the tasks in this WA. These reports should also indicate an estimate for the next month by task and if any lagging costs are expected. EPA realizes these estimates are just approximate values and is interested in having this information for internal budgeting purposes.

Task 1.2: Information Quality Guidelines

The Contractor shall ensure the products developed under this work assignment comply with the EPA Information Quality Guidelines and shall complete the Checklist for Influential Information as needed for each deliverable from this work assignment as they may be used in Agency decision-making and/or will be publicly available documents. The EPA WAM will provide the checklist to the Contractor. The Contractor shall provide a memorandum describing how the planned product(s) developed meet EPA's Information Quality Guidelines checklist. As part of that memo, the Contractor shall document the quality assurance procedures it used in

developing the deliverables under this Work Assignment. The Contractor shall provide the memo at the time it delivers the Final Summary Report. As directed by the EPA WAM, the Contractor shall have a teleconference with the EPA WAM to discuss the Guidelines and the Contractor's role in completing the checklist.

Task 2: General Project Support and Development of Technical Support Guidance

EPA is planning to make available Quantitative Microbial Risk Assessment (QMRA) guidance to States for consideration in developing site-specific Water Quality Standards (WQS) packages. Task 2 comprises the different facets of the QMRA guidance project and includes project planning, communication strategies, and guidance document development.

Task 2.1: Project planning and management

The Contractor shall conduct project strategic planning in conjunction with the EPA WAM. The purpose of this subtask will be to develop a comprehensive plan that includes all related tasks and deliverables in the context of the Agency's Recreational Ambient Water Quality Criteria (RWQC) and implementation guidance. The planning shall include a discussion of how each task will aid EPA in meeting its goals in relation to QMRA and the technical support guidance for implementation.

This task may require contractor travel to HQ for an initial planning meeting and quarterly update meetings thereafter during the period of performance of this work assignment. All appropriate clearances and approvals required by Agency policy in support of any and all conference related activities and expenses, including support of meetings, conferences, training events, award ceremonies and receptions, shall be obtained by the EPA PO as needed and provided to the Contracting Officer. Work under conference related activities and expenses shall not occur until this approval is obtained and provided by the PO.

The Contractor shall provide personnel knowledgeable in QMRA and also project planning and management for this process. Expertise in Microsoft Project (v. 2007) is preferred. The initial meeting is crucial to the entire overall work assignment and therefore will need to occur soon after the work assignment is received by the Contractor. Additionally, weekly update meetings between the EPA WAM and the Contractor shall be scheduled.

Deliverables under this subtask will include updating (as needed) schedules listing all QMRA-related work with interim and final deliverable dates and quarterly project updates delineated. Given that the various QMRA tasks, both previously conducted by HECD and under the current effort, have been conducted incrementally, these pieces fit together to form a substantive body of work for the Agency.

As part of the effort under this subtask, the Contractor shall include a discussion on the Agency's QMRA goals and objectives and how each of the tasks supports them. It is hoped that this exercise will also help to identify any gaps that will need to be addressed prior to the publication of the implementation guidance. Project milestones provided in this work

assignment may be impacted by the results of this project planning. Any differences identified in these due dates will need to be identified and communicated via technical direction from the EPA WAM.

Task 2.2: Project communication support:

The contractor shall, based on technical direction given by the EPA WAM, provide support in preparing interim project updates and other materials for internal and external audiences. These may include but are not limited to short briefing documents and PowerPoint presentations. The Contractor may also be directed to participate in and/or conduct briefings and meetings. The Contractor may also be directed to prepare reports for communication outside the EPA based on deliverables generated by tasks under this work assignment. The Contractor shall coordinate with the EPA WAM for the proper timing and need for these activities. A weekly update call with the EPA WAM will be required for this task, as needed.

A second major area under this task is QMRA outreach support. The Contractor shall assist EPA WAM with internal and external outreach to EPA management, both at Headquarters and with Regional offices, States, and other Stakeholder groups.

EPA needs to communicate its efforts to a broad audience. From engaging other scientists on technical issues to discussing regulatory actions with stakeholders and the public, EPA needs to be keenly aware of effective communication strategies. For all tasks under this work assignment, the Contractor shall discuss with the EPA WAM ways to achieve effective communication objectives. The audience for specific deliverables may be different even though the analytical approach may be similar. Questions to cover with the EPA WAM should address the audience and purpose of the deliverable, ideas for finding effective presentation strategies, suggestions for achieving the communication objectives given differing formats (e.g., written versus oral).

The Contractor may be requested to attend meetings of a scientific nature to present the results of the QMRA analyses to technical and non-technical audiences. All appropriate clearances and approvals required by Agency policy in support of any and all meetings shall be obtained by the EPA PO as needed and provided to the Contracting Officer. Work under meeting-related activities and expenses shall not occur until this approval is obtained and provided by the PO. Known at the time of submission of this work assignment is the following:

Conference – 2014 Water Microbiology Conference: Microbial Contaminants from Watersheds to Human Exposure

University of North Carolina at Chapel Hill, Chapel Hill, NC

The Contractor shall engage with the EPA WAM to prepare poster presentation(s) of appropriate QMRA topics from the completed and ongoing tasks. The deadline for submission of abstracts is January 13, 2014.

Task 2.3: Development of QMRA Technical Support Guidance, QMRA framework:

The purpose of this task is to continue development and to produce communication materials for the use of QMRA in the development of site-specific recreational water criteria intended as the basis for water quality standards (WQS). Past efforts by the Contractor have concentrated mainly on non-human sources, but the framework itself should be robust enough to consider other differences or site-specific characteristics.

The Contractor shall continue development of the Quantitative Microbial Risk Assessment (QMRA) framework for the purposes outlined above. This task shall build upon previous efforts conducted under B-04, Task 2.2 (QMRA guidance: how to conduct a QMRA for ambient waters, data needs and analytical approaches), and 1-04 and 2-04, Task 2.3. The goal for this task will be to develop and to communicate the process by which QMRA can be used to derive alternative site-specific ambient water quality criteria for recreational use waters that will, in turn, be used to assemble a water quality standards (WQS) package. This deliverable can be considered part of the overall technical support guidance as detailed in other tasks below, and shall include a description and discussion of the process and framework whereby QMRA could be used as a basis for a site-specific WQS package.

The deliverable shall address the way(s) a State can determine if any given site is a good candidate for the development of a site-specific water quality standards package based on a QMRA-derived criteria value. The Contractor shall include a discussion of the components of water quality standards package and how QMRA can assist in developing a site-specific water quality criteria value. To complete this part of the deliverable, the Contractor shall meet with the EPA WAM, WQS coordinators or other personnel in SHPD and the Regions. Logistics of these meetings may require the Contractor to attend meetings at EPA HQ. The Contractor shall address the differing approaches a State could use in running a QMRA (i.e., differing level of effort related to complexity of analysis).

The Contractor shall also consider the implications that the WQS package will be evaluated by EPA regional and headquarters personnel who will not necessarily have a technical background in microbiology, public health or risk assessment methodologies. Therefore, it will be **critical** that the Contractor consider the end-user audience as the deliverable is being developed. Technical material shall be transparently and sufficiently conveyed. The narrative shall be thoroughly developed and any graphical materials shall be explained completely. No assumption should be made that the audience will internalize figures or tables. These considerations are quite important as this material will be used to inform the policy decisions needed for QMRA to be used effectively. Much consideration should be given to the current paradigm in this area; end-users that are not familiar with risk assessment in general and hampered by misunderstandings related to the past and current technical bases for the nationally recommended recreational water quality criteria. It will be crucial that the Contractor develop effective communication and outreach materials if QMRA is to be applied effectively.

Task 2.4: Development of QMRA Technical Support Guidance, Volume A:

The purpose of this task is to develop a guide for use by States and localities for the purposes of deriving via the QMRA framework discussed in Task 2.3, site-specific criteria, notably for waters predominated by non-human sources of fecal contamination, for inclusion into WQS. This volume will need to be published by the Agency during 2014, so the Contractor will need to plan accordingly. This timeframe also includes substantial time for management and 3rd party peer review.

This guide should also provide information to EPA Regions who are tasked to evaluate State WQS packages. Volume A of this guidance shall concentrate on how to determine if a water body is eligible for the development of site-specific criteria, what information can be used to provide a line of evidence approach for determining sources of fecal contamination (i.e., how to build a sanitary characterization), differing approaches to conducting a Quantitative Microbial Risk Assessment (QMRA) (i.e., incorporate information from Task 2.3), the information needs for conducting a QMRA (at each level of effort), how to conduct a QMRA (i.e., how to build a transparent, clear, concise and reasonable risk assessment in support of public policy), deriving a site-specific water quality criterion, preparing a site-specific water quality standards package, and other topics as needed to be specified by the EPA WAM (and in consultation with HECD's partners in SHPD). The main goal for this deliverable is produce guidance for States to use in developing microbial Water Quality Standards (WQS) that are scientifically defensible, protective of the recreational designated use, and meet EPA standards for consideration and potential approval.

This task will require the Contractor to attend meetings with the EPA WAM and other staff at EPA Headquarters during the period of performance for the purposes of project updates, planning and communication. The Contractor shall anticipate travel to DC once per quarter for a total of 4 meetings at EPA HQ.

All appropriate clearances and approvals required by Agency policy in support of any and all conference related activities and expenses, including support of meetings, conferences, training events, award ceremonies and receptions, shall be obtained by the EPA PO as needed and provided to the Contracting Officer. Work under conference related activities and expenses shall not occur until this approval is obtained and provided by the PO.

Task 2.5: Development of QMRA Technical Support Guidance (TSG), Volume B:

The deliverable under this task shall provide the end user a sufficiently detailed background on QMRA and the use of microbial risk assessment in developing site specific water quality standards. This volume shall provide the technical bases for the material in Volume A (Task 2.4). While this volume is purposefully technical in nature, it should still be produced in a manner that would be accessible to the end user. This volume is also scheduled to be published during 2014.

The Contractor shall include the following topics in the scope of technical materials: assessing human health risks from fecal contamination in surface waters; use and application of epidemiology in development of water quality standards around the world; use of risk assessment to help interpret and extend observational studies; factors affecting occurrence, prevalence, fate and transport of pathogens and fecal indicator bacteria in surface waters; potential effects of management practices on sources of fecal contamination and implications to potential human health risks; and, other topics as specified by the EPA WAM.

Task 2.6: Development of QMRA Technical Support Guidance (TSG), Volume C:

The purpose of this task is to document a series of QMRAs conducted on recreational use waters. Each QMRA would be made available or peer reviewed/published separately. This volume will discuss each and give more information to explain how each risk assessment fits into context with the materials in volumes A and B. The context that will need to be developed will consist of a compare and contrast discussion with EPA recommended ambient water quality criteria for recreational waters and other risk assessments. The Quantitative Microbial Risk Assessments (QMRAs) can be discussed as 'case studies'. This compilation volume will be peer reviewed with Vol B and should be considered to be on the same schedule for completion.

At present, the EPA WAM envisions this "volume" to comprise a report and will reference the risk assessments discussed and where to find them (should copyrights allow, those assessments can be included as appendices). Existing material for inclusion in this volume includes: Ohio case study; Boqueron case study, Chicago Area Waterways (CAWS) case study, and Southern California Coastal Water Research Project (SCCWRP) case study. However, the SCCWRP case study may occur on a parallel track and not be complete in time for a full discussion in Volume C. The Contractor shall coordinate with the EPA WAM early and often to better scope out other potential material for this volume.

The Contractor may be required to attend meetings with SCCWRP to discuss planning, scoping, conduct, or analyses associated with the case study project. As mentioned before, all appropriate clearances and approvals required by Agency policy in support of any and all conference related activities and expenses, including support of meetings, conferences, training events, award ceremonies and receptions, shall be obtained by the EPA PO as needed and provided to the Contracting Officer. Work under conference related activities and expenses shall not occur until this approval is obtained and provided by the PO.

Task 2.7: Support for Southern California Coastal Water Research Project (SCCWRP) case study

The LA Regional Water Control Board, SCCWRP and EPA are collaborating on a project to characterize human health risks via QMRA from recreational water exposure at a predominantly non-human fecal-impacted beach in southern California. The potential beach locations are in Southern California. The second main goal of this effort is to use the QMRA results to inform the development of a site-specific water quality standard for submission and evaluation by EPA Region 9. The third goal of this effort is to document the experience as a "case study" for potential application at other candidate sites.

The Health and Ecological Criteria Division's participation in this project will be to aid in the planning and scoping of the project, provide QMRA support, and engage the regional water control board, EPA Region 9, and the local NGOs in the development and evaluation of a site-specific water quality standard package. The Contractor shall assist the EPA WAM with the QMRA-related aspects of this project. The Contractor shall participate in discussions with the EPA WAM along with SCCWRP and the workgroup to help with project planning, scoping, QMRA analysis, interpretation of the results, and development of communication strategies for the purpose of deriving site-specific recreational water criteria for a beach predominantly impacted by non-human fecal contamination. QMRA-related efforts under this task should help to inform activities under Task 2.6. The Contractor shall discuss the practical experiences learned from this project to help improve, refine, or change the current approach detailed in the TSM.

This task is considered complete, but continued engagement with SCCWRP and other interested parties, such as the CA state and/or regional waterboards, may be requested to aid in the interpretation of the technical results and policy implications.

Task 2.9: Updating the Microbial Risk Assessment Tools Document

OST previously prepared a microbial risk assessment (MRA) document specifically for water media. This document has been through internal editing and peer review by the EPA's Science Advisory Board. The draft is currently under EPA review. The Contractor shall incorporate any comments based on this review and prepare the document for final approval and publication.

The revised document should need a final internal QA check by the Contractor prior to submission to the EPA WAM. The Contractor has developed a briefing package for the document to be used in communicating with internal EPA management in the document approval process during the previous contract year. The briefing package may need additional edits to tailor it for specific audiences.

Task 3: QMRA anchoring

Task 3.1: Marine National Epidemiological and Environmental Assessment of Recreational Water (NEEAR) studies

A revised report was submitted by the Contractor on 12/15/13. The Contractor may need to update the report to reflect EPA comments prior to this report being inserted into the TSM Vol C appendix. Once updated (as discussed below), the Contractor shall also submit as part of the revised draft a project summary aimed at a non-technical audience. The summary should provide the important conclusions to be drawn from the analysis along with a discussion of how these results fit into context with the existing knowledgebase (not necessarily restricted to the area of QMRA).

Task 3.2: Marion et al. study

This task is still ongoing. Upon receiving comments from the EPA WAM, the Contractor shall forward the revised report to the Ohio State University collaborators for their review. After that is complete, an updated report suitable for internal management review shall be submitted to EPA WAM within two weeks of receiving OSU input. Comments from this review shall be discussed with the EPA WAM and the report revised accordingly. A final report suitable for peer review shall be submitted to EPA WAM by the end of March 2014.

This collaboration provides an excellent opportunity for the EPA to engage with external researchers. The Contractor shall assist in maintaining the good relationship EPA has established with the OSU staff. Any ideas for improving this collaboration will be quite welcome to the EPA WAM. Additionally, the contractor may be requested to provide facilitation assistance with the OSU group in order to maintain sufficient progress towards peer reviewing the QMRA deliverable.

Task 3.3: Boqueron

The Contractor received comments from EPA WAM on the submitted draft report on 11/06/12. The Contractor is currently updating this document at the time of the submission of this work assignment. The updated version will need to be cleared by EPA management prior to submission for publication. Any comments from this review shall be discussed with the EPA WAM and the report revised accordingly. A final report suitable for submission to a peer review journal shall be submitted to the EPA WAM when these revisions are complete.

Task 3.4: QMRA anchoring communication support

The Contractor shall develop communication materials for each of the task 3 QMRA reports aimed at non-technical, policy-oriented audiences. Materials aimed at the general population may also be needed and shall be prepared by the contractor when technical direction is received. The Contractor shall discuss the importance of the findings of the Task 3 efforts, how they fit into context with other QMRA and other results, and any science or policy implications. Other topics to be included in these materials will be discussed as needed with the Contractor.

Additionally, the Contractor may be required to attend one meeting at EPA Headquarters to present results to management and staff. Timing for the meeting has not been finalized at the time of the submission of this work assignment; however, ODCs for one visit to EPA Headquarters are included.

Task 4: Relative QMRA refinement

Task 4.1: Evaluating source and receptor locations

This task shall continue support for efforts begun under B-04. The contractor shall meet with the EPA WAM to develop a list of modeling needs (e.g., FRAMES-related) to support implementation of QMRA. The contractor shall also coordinate with the EPA WAM to discuss

with other EPA personnel about advancements in dose response modeling (e.g., animal studies translated to human health estimates).

The contractor shall continue to discuss with the EPA WAM and ORD-Athens personnel the current capabilities for fate and transport modeling in the context using the QMRA framework for deriving water quality standards. HECD will need to have these discussions documented for use with communication with management. This task is considered to require a low level of effort during the period of performance.

Task 4.2: Relative QMRA refinement: QMRA analysis of mixed fecal sources

The Contractor submitted a report for EPA management review in the last contract year. This report is still under review at this time.

The Contractor shall update the report incorporating EPA WAM's comments. Comments from this review shall be discussed with the EPA WAM and the report revised accordingly. A final report suitable for peer review shall be submitted to the EPA WAM when these revisions are complete.

Task 5: Primary and Secondary Contact evaluations

The purpose of this task is to evaluate health risks associated with different water-based activities performed in the US. This task will be part of the scientific basis for policy measures to place activities into appropriately protective recreational use categories (e.g. primary contact recreation, secondary contact recreation), and to determine the level of water quality necessary to protect individuals engaging in each of these activities.

The Contractor submitted a draft Quantitative Microbial Risk Assessment (QMRA) report during the base year under this task. For this work assignment, the Contractor may be asked to provide responses to questions from EPA WAM on the analysis and conclusions contained in the deliverable. The Contractor may also be requested to update this document prior to its inclusion in Volume C (Task 2.6).

Task 6: Children's Health, Sensitive Subpopulations, Alternate Study designs, and Environmental Justice evaluations

Task 6.2: Alternate epidemiology study designs

EPA is interested in comparing results from epidemiology studies conducted with alternative study designs. The Agency has conducted past efforts in this area to identify appropriate data sets and design an analytical approach for that data. The Contractor shall build upon those past efforts and secure data from an RCT (randomized control trial) epidemiology study sufficient for a comparative analysis with a PC (prospective cohort) design. The Contractor shall conduct the following activities:

Coordinate with the investigators on an RCT study to obtain the raw data from that study and re-analyze the results using the statistical methods employed by Wade and colleagues for the EPA epidemiology studies. This analysis will provide an indication of whether or not results from RCTs and PCs can be compared directly and will help to answer the question of whether the differences observed in existing epidemiology studies are due to the study design or other factors.

Use a QMRA framework to translate results from an RCT to one that is comparable to a PC study. Conduct sensitivity analyses to identify the model parameters that most strongly influence the results. Compare the results with those from the first analysis. The contractor shall report findings to EPA WAM in a memorandum, including potential next steps for this analysis.

Efforts conducted in the base year resulted in the identification of potential datasets for this analysis. However, there has been reluctance from external researchers to share the data needed for this comparison. This subtask is included here to maintain the potential for this analysis in this option year, but the Contractor should consider this subtask as a placeholder and low priority. Should data become available, the Contractor shall discuss the path forward with the EPA WAM before any LOE is expended on this task.

Task 7: Chicago Area Waterways (CAWS) QMRA

The goal of this task is to develop a QMRA-based evaluation of human health risks from exposure to the Chicago Area Waterways. This evaluation should consider the range of exposures covered by the traditional metrics of primary and secondary contact recreation.

The Contractor submitted a draft QMRA using both literature-reported values for pathogens in secondary treated, but non-disinfected effluent and the results from pathogen monitoring on the CAWS.

There is considerable interest within EPA, both at HQ and in Region 5, in this particular QMRA. While this is not a high priority, the Contractor may be requested to visit Region 5 in order to discuss other potential analyses. This visit is not definite, but ODCs have been included in case the need for the meeting materializes.

The Contractor shall revise the draft report as needed prior to its inclusion in Volume C (Task 2.6). The Contractor shall also submit a final version of the report to the EPA WAM within two weeks of receiving any EPA comments.

The Contractor shall submit technical and non-technical briefing materials along with the revised assessment. These materials may be a "two-pager" and/or a slide presentation and will be discussed during the weekly meeting.

Milestone/Deliverable Table

Task	Task #	Milestones and Due Dates
Task 1: Work plan, monthly progress reports and quality assurance		
Workplan	1.1	Within 15 calendar days of receipt of work assignment
Information Quality Guidelines	1.2	Discuss with EAP WAM within 15 calendar days of receipt of work assignment. IQG checklists due with final deliverable (can be included with QA materials).
Task 2: General Project Support		
Project Planning and Management	2.1	Initial planning meeting to be held within 15 calendar days of receipt of work assignment. Meeting shall update project Gantt chart, goals and objectives statement, and gap analysis due within 2 weeks of initial meeting. Drafts of this deliverable would be expected at the close of the initial meeting. Subsequent meetings to be held roughly every quarter thereafter.
Project Communications Support	2.2	After the workplan approval, throughout the period of performance. See meeting dates in WA text. Other communication materials will be dependent on the analytical results. Revisions to the P4 paper due within 2 weeks of receiving comments from OW and ORD.
QMRA TSG: QMRA Framework	2.3	Include as part of Volume A..
QMRA TSG: Vol A	2.4	Draft for mgmt review – 2 weeks after WP approval; Draft for peer review – 1 week after receiving EPA comments; Final draft for mgmt review – 2 weeks after receiving peer review comments; Final – 1 week after receiving mgmt comments and approval.
QMRA TSG: Vol B	2.5	Same schedule as Vol A.

QMRA TSG: Vol C	2.6	Vol C mainly consists of reports prepared individually under other tasks - refer to those tasks for component schedules. Respond to reviewer comments as needed. For supplemental text expanding on those reports: same schedule as Vol A.
Support for SCCWRP study	2.7	Provide QMRA related planning, scoping, analysis, interpretation, and site-specific standard derivation support. Attend workgroup meetings at SCCWRP approximately once per year. Ongoing low level of effort throughout the period of performance.
Task 3: QMRA Anchoring		
Marine NEEAR reverse QMRA	3.1	Updated report needed to fit into Vol C schedule. Discuss incorporation of results into TSM Vol C. Follow Vol C schedule.
Marion anchoring QMRA	3.2	Update report based on EPA and OSU comments and other analyses, with 2 weeks of receiving OSU input. Updated draft will be reviewed by HECD management. Mgmt comments will be addressed and final report to be submitted for peer review by end of March, 2014.
Boqueron QMRA	3.3	Updated draft within 1 month of receiving EPA comments. Updated draft will be reviewed by HECD mgmt. Mgmt comments will be addressed and final report to be submitted for peer review by end of January, 2014.

QMRA Communications Support	3.4	Non-technical, policy oriented communication materials, within 1 month of workplan approval. Materials for general audiences due date to be determined by technical direction. Meeting and presentation at EPA HQ to be determined.
Task 4: Relative QMRA refinement		
Evaluating sources and receptor locations	4.1	Ongoing throughout the period of performance. Periodic teleconference calls (e.g., bimonthly) with HECD, ICF, and ORD-Athens. Deliverables for this task include notes of teleconference meetings and synopses of modeling developments and capabilities used for internal communication.
Refinement of QMRA analyses of mixed fecal sources	4.2	Updated report within 2 weeks of receiving EPA comments. Mgmt comments will be addressed and final report to be submitted for peer review.
Task 5: Primary and Secondary Contact		
Communications support		Moderate LOE effort; as needed throughout the period of performance.
Task 6: Sensitive Subpopulations and alternate study designs		
Alternative epidemiology study design	6.2	Low LOE effort; continue efforts to identify RCT data sets.
Task 7: CAWS QMRA support		
Update draft QMRA addressing EPA comments and inclusion of additional questions/information.	7.1	Updated report based on EPA comments due within 2 weeks of receiving comments from EPA HQ and Region 5. Discuss incorporation of report into TSM Vol C. Follow Vol C schedule.

General Requirements of the Work Assignment and Schedule:

Due Dates: The Contractor shall provide due dates that are mutually acceptable with the EPA WAM. The Contractor shall notify the EPA WAM in advance, if a due date will not be met and request a revised date.

Delays: The Contractor shall make every effort to ensure there are no Contractor-caused delays. If a delay is inevitable, it is the Contractor's responsibility to notify the EPA WAM at the first sign of said delay. A revised schedule will then be worked out.

Draft Documents: The Contractor may be required to submit draft documents. Draft documents shall be prepared in an electronic format compatible with current Microsoft products. EPA WAM will provide comments on draft submissions prior to submission of final documents.

Final Documents: The Contractor shall submit final documents both electronically and in hardcopy to EPA WAM.

Attachment 1

QAPP REQUIREMENTS FOR PROJECTS USING SECONDARY DATA

A secondary data project involves the gathering and/or use of existing environmental data for purposes other than those for which they were originally collected. These secondary data may be obtained from many sources, including literature, industry surveys, compilations from computerized databases and information systems, and computerized or mathematical models of environmental processes. For these projects, a QAPP shall be prepared to include the requirements identified below. If primary data will also be generated as part of the project, then the information below can be incorporated into the associated QAPP to address the secondary data. The following requirements should be addressed as applicable.

SECTION 1.0, PROJECT OBJECTIVES, ORGANIZATION, AND RESPONSIBILITIES

- 1.1 The purpose of study shall be clearly stated.
- 1.2 Project objectives shall be clearly stated.
- 1.3 The secondary data needed to satisfy the project objectives shall be identified. Requirements relating to the type of data, the age of data, geographical representation, temporal representation, and technological representation, as applicable, shall be specified.
- 1.4 The planned approach for evaluating project objectives, including formulas, units, definitions of terms, and statistical analysis, if applicable, shall be included.
- 1.5 Responsibilities of all project participants shall be identified, meaning that key personnel and their organizations shall be identified, along with the designation of responsibilities for planning, coordination, data gathering, data analysis, report preparation, and quality assurance, as applicable.

SECTION 2.0, SOURCES OF SECONDARY DATA

- 2.1 The source(s) of the secondary data must be specified.
- 2.2 The rationale for selecting the source(s) identified shall be discussed.
- 2.3 The sources of the secondary data will be identified in any project deliverable.

SECTION 3.0, QUALITY OF SECONDARY DATA

- 3.1 Quality requirements of the secondary data must be specified. These requirements must be appropriate for their intended use. Accuracy, precision, representativeness, completeness, and comparability need to be addressed, if

applicable. (If appropriate, a related QAPP containing this information can be referenced.)

3.2 The procedures for determining the quality of the secondary data shall be described.

3.3 If no quality requirements exist, this shall be stated in the QAPP. If no quality requirements exist or if the quality of the secondary data will not be evaluated by EPA, the QAPP shall require that a disclaimer be added to any project deliverable to indicate that the quality of the secondary data has not been evaluated by EPA for this specific application. The wording for the disclaimer shall be defined.

SECTION 4.0, DATA REPORTING, DATA REDUCTION, AND DATA VALIDATION

4.1 Data reduction procedures specific to the project shall be described, including calculations and equations.

4.2 The data validation procedures used to ensure the reporting of accurate project data shall be described.

4.3 The expected product document that will be prepared shall be specified (e.g., journal article, final report, etc.).

Attachment 2

QAPP Requirements for Research Model Development and Application Projects

GENERAL REQUIREMENTS: Include cover page, distribution list, approvals, and page numbers.

0. COVER PAGE (MODEL DEVELOPMENT AND MODEL APPLICATION)

Include the Division/Branch, project title, revision number, EPA technical lead, QA category, organization responsible for QAPP preparation, and date.

1. PROJECT DESCRIPTION AND OBJECTIVES (MODEL DEVELOPMENT AND MODEL APPLICATION)

In this document, "project" can mean (a) development or substantial modification of a model for application to address a general problem; (b) application of an existing model (including minor modification to the existing model) to address a specific problem; or (c) a development or substantial modification and application of a model to address a specific problem.

- 1.1 State the purpose of the project and list the project objective(s). Indicate whether a new model will be developed or an existing model will be used.
- 1.2 Describe the problem, the data to be generated by the model, how the data will be used to address the problem, and the intended users of the data. Describe the environmental system/setting to be modeled, where the model will be applied, and the circumstances and scenarios to be considered for the modeled system.

2. ORGANIZATION AND RESPONSIBILITIES (MODEL DEVELOPMENT AND MODEL APPLICATION)

- 2.1 Identify all project personnel, including QA, and related responsibilities for each participating organization, as well as their relationship to other project participants.
- 2.2 Include a project schedule that includes key milestones.

3. MODEL SELECTION (MODEL APPLICATION ONLY)

- 3.1 Discuss model selection with respect to how it will be used and how it is consistent with the project objectives. Include fundamental details such as whether the model will be used to predict the world beyond the model or in scenario analysis of the model itself. Describe the limits to where the model is applicable.
- 3.2 Provide a description of the model attributes/capabilities required for the project. This description should include hardware requirements and restrictions. Provide an overview of the candidate model attributes, including:

- model origin and its original purpose, if applicable
 - model structure (e.g., stochastic vs. deterministic, structural framework)
 - parameters and variables
 - the algorithms and equations that have been developed to support the model theory, along with the sources of the algorithms
 - spatial extent (individual, group, population)
 - spatial resolution (location independent/dependent, dimensionality)
 - temporal extent (length of modeling period)
 - temporal resolution (time step)
- 3.3 Identify the model to be used or, if the model has not yet been selected, describe the process to be used for the selection of an existing model.
- 3.4 Identify specific requirements for application of the selected model for this specific purpose (e.g., current and appropriate data, parameter values, assumptions).

4. MODEL DESIGN (MODEL DEVELOPMENT ONLY)

- 4.1 Describe the conceptual model(s) for the system, including model parameters.
- 4.2 Identify algorithms and equations that have been developed to support the model theory, or if such equations are not already available, describe the process used to develop these equations.
- 4.3 Specify required sources for model databases and any requirements for these data (e.g., quality, quantity, spatial, and temporal applicability). If data sources are not currently known, describe the criteria used to identify sources. Describe how any data gaps will be filled.

5. MODEL CODING (MODEL DEVELOPMENT ONLY)

- 5.1 Discuss the requirements for model code development, where applicable.
- 5.2 Identify computer hardware and software requirements.
- 5.3 Discuss requirements for code verification.

6. MODEL CALIBRATION (MODEL DEVELOPMENT AND MODEL APPLICATION)

Calibration is the process of adjusting model parameters within physically defensible ranges until the resulting predictions give the best possible or desired degree of fit to the observed data. Calibration should be applied each time the model is modified.

- 6.1 Discuss how the model will be calibrated.
- 6.2 Identify the type and source of data (e.g., new data, existing data, professional judgment, expert opinion elicitation) that will be used to calibrate the model, including any requirements for the data (quality, quantity, and spatial and temporal applicability). If data sources are not currently known, describe the criteria used to identify sources.
- 6.3 Specify acceptance criteria which need to be met for the difference between

predicted and observed data during model calibration, where applicable. The statistical methods (e.g., goodness-of-fit, regression analyses) or expert judgment to be used should also be discussed.

7. MODEL VERIFICATION (MODEL DEVELOPMENT AND MODEL APPLICATION)

Verification consists of comparing the predictions of a calibrated model with available data that were not used in the model development and calibration.

- 7.1 Discuss the approach to be used for model verification. Describe how the verification is appropriate based on the model's purpose. Identify the type and source of data (e.g., new data, existing data, synthetic test data sets, professional judgment, expert opinion elicitation) that will be used to verify the model. If data sources are not currently known, describe the criteria used to identify sources.
- 7.2 Discuss the characterization of model uncertainty (model framework, model input, and model applicability) and sensitivity (model application only).
- 7.3 Describe any requirements (quality, quantity, and spatial and temporal applicability) for the data that will be used to verify the model.
- 7.4 Describe the approach used to determine if the independent data verify the model predictions. Specify the criteria which need to be met for the difference between predicted and observed data for the model to be considered to be verified. Discuss any statistical methods to be used (e.g., goodness-of-fit, regression analyses).

8. MODEL EVALUATION (MODEL DEVELOPMENT AND MODEL APPLICATION)

- 8.1 List and describe the qualitative or quantitative assessment process to be used to generate information to determine whether a model and its analytical results are of a quality sufficient for the intended use.
- 8.2 List and describe any independent/external evaluation and review of the model and model design, such as scientific peer review.

9. MODEL DOCUMENTATION (MODEL DEVELOPMENT AND MODEL APPLICATION)

Specify the requirements for model documentation. Good documentation includes:

- final model description, final model specifications (model development only), hardware and software requirements, including programming language, model portability, memory requirements, required hardware/software for application, data standards for information storage and retrieval
- the equations on which the model is based (model development only)
- the underlying assumptions
- flow charts (model development only)

- description of routines (model development only)
- data base description
- source code (model development only)
- error messages (model development only)
- parameter values and sources
- restrictions on model application, including assumptions, parameter values and sources, boundary and initial conditions, validation/calibration of the model, output and interpretation of model runs (model development only)
- the boundary conditions used in the model
- limiting conditions on model applications, detail where the model is or is not suited
- changes and verification of changes made in code
- actual input data (type and format) used
- overview of the immediate (non-manipulated or -post processed) results of the model runs (model application only)
- output of model runs and interpretation
- user's guide (electronic or paper)
- instructions for preparing data files (model development only)
- example problems complete with input and output
- programmer's instructions
- computer operator's instructions
- a report of the model calibration, validation, and evaluation (model development only)
- documentation of significant changes to the model
- procedures for maintenance and user support, if applicable

10. REPORTING (MODEL DEVELOPMENT AND MODEL APPLICATION)

- 10.1 List and describe the deliverables expected from each project participant.
- 10.2 Specify the expected final product(s) that will be prepared for the project (e.g., journal article, final report).

11. REFERENCES

Provide the references either in the body of the text as footnotes or in a separate section.

EPA United States Environmental Protection Agency Washington, DC 20460 Work Assignment		Work Assignment Number 3-04								
		<input type="checkbox"/> Other <input checked="" type="checkbox"/> Amendment Number: 000001								
Contract Number EP-C-11-005		Contract Period 01/01/2011 To 12/31/2014 Title of Work Assignment/SF Site Name QMRA activities to support								
Contractor ICF Incorporated, L.L.C.		Specify Section and paragraph of Contract SOW 3.1, 3.3, 3.6								
Purpose: <input type="checkbox"/> Work Assignment <input type="checkbox"/> Work Assignment Close-Out <input checked="" type="checkbox"/> Work Assignment Amendment <input type="checkbox"/> Incremental Funding <input type="checkbox"/> Work Plan Approval		Period of Performance From 01/01/2014 To 12/31/2014								
Comments:										
<input type="checkbox"/> Superfund		Accounting and Appropriations Data								
		<input checked="" type="checkbox"/> Non-Superfund								
Note: To report additional accounting and appropriations data use EPA Form 1900-69A.										
SFO (Max 2) <input type="checkbox"/>										
Line	DCN (Max 6)	Budget/FY (Max 4)	Appropriation Code (Max 6)	Budget Org/Code (Max 7)	Program Element (Max 9)	Object Class (Max 4)	Amount (Dollars)	(Cents)	Site/Project (Max 8)	Cost Org/Code (Max 7)
1										
2										
3										
4										
5										
Authorized Work Assignment Ceiling										
Contract Period:		Cost/Fee:				LOE:				
01/01/2011 To 12/31/2014										
This Action:										
Total:										
Work Plan / Cost Estimate Approvals										
Contractor WP Dated:		Cost/Fee:				LOE:				
Cumulative Approved:		Cost/Fee:				LOE:				
Work Assignment Manager Name John Ravenscroft						Branch/Mail Code:				
_____ (Signature) _____ (Date)						Phone Number 202-566-1101				
						FAX Number:				
Project Officer Name Shirley Harrison						Branch/Mail Code:				
_____ (Signature) _____ (Date)						Phone Number: 202-566-1107				
						FAX Number:				
Other Agency Official Name Shirley Harrison						Branch/Mail Code:				
_____ (Signature) _____ (Date)						Phone Number: 202-566-1107				
						FAX Number:				
Contracting Official Name Sandra Stargardt-Licis						Branch/Mail Code:				
_____ (Signature) _____ (Date)						Phone Number: 513-487-2006				
						FAX Number:				

**Performance Work Statement
ICF Contract # EP-C-11-005
Work Assignment #3-04 Amendment 1**

Title: QMRA Activities to Support Criteria Development and Implementation

**Work Assignment Contracting:
Officer Representative (WACOR)** John Ravenscroft (Mail Code 4304T)
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Alternate WACOR: Sharon Nappier (Mail Code 4304T)
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Contractor PWS: 3.1, 3.3, and 3.6

Period of Performance: WA Amendment Issuance through December 31, 2014

****Note:** No CBI data will be needed in the course of this work assignment.

Purpose of Amendment: The purpose of this amendment is to provide additional LOE and funding for the existing Task 2, 3, 4, and 7. Multiple deliverables under these tasks have necessitated additional rounds of review and editing that were not anticipated when the original work assignment was prepared. The additional LOE and funding supplied by this amendment will help to prepare useful deliverables of sufficient quality for EPA and maintain project timelines.

Unless specifically mentioned, the language contained in the original work assignment still applies (e.g., Information Quality Guidelines, QA section, etc.). All deliverables and deliverable dates remain unchanged. The contractor shall submit a cost estimate for this amendment.

Task 2: General Project Support and Development of Technical Support Guidance

Task 2.2: Project communication support:

Additional funds are provided so the contractor can continue to provide HECD with support for preparing project updates and other materials for internal and external audiences. The contractor shall continue to provide support the WACOR with internal and external outreach to EPA management, both at Headquarters and Regional offices, States, and other Stakeholder groups. The contractor shall continue to meet with the WACOR regularly to provide project updates and conduct project management.

Tasks 2.3, 2.4, 2.5 and 2.6: Development of QMRA Technical Support Guidance:

The QMRA technical support guidance is currently undergoing internal management review prior to external peer review. Additional funds are provided so the contractor shall address management comments and prepare the documents for external peer review, including completing the QA checklist. The contractor, will provide support to EPA, to review in conjunction with the WACOR and OST staff and respond to peer review comments, provide a written justification to document and how each comment was addressed. The contractor shall prepare the final document for management review, support the WACOR in responding to comments and prepare the document, and any supporting materials, for publication. EPA expects to publish the documents before December 2014.

Task 2.7: Support for Southern California Coastal Water Research Project (SCCWRP) case study

Additional funds are provided to continue contractor support for the collaboration between SCCWRP and EPA on efforts to characterize human health risks via QMRA from recreational water exposures at beaches impacted by non-human sources of fecal contamination. SCCWRP is continuing to study human health risks from recreation at Southern California beaches. The contractor shall provide EPA support on QMRA evaluations of the results of SCCWRP health studies.

Task 2.9: Updating the Microbial Risk Assessment Tools Document

The contractor submitted a final version of the "Tools" document to the WACOR. Additional funds are provided for the contractor to provide support in the final stages prior to the publication of the document. For example, there may be additional management comments to address prior to publication, there may be a need to prepare communication materials to accompany the final deliverable, etc. While publication of this document is a near-term priority, the contractor support on this task is not considered to be significant.

Task 3: QMRA anchoring

Task 3.2: Marion et al. study

The contractor shall provide technical support to the WACOR to prepare a manuscript suitable for publication in a peer-reviewed journal based on the QMRA analysis of the East Fork Lake epidemiological study conducted by Ohio State University. The contractor has previously submitted a draft report under the previous option year. This effort is a near-term priority and a draft manuscript of sufficient quality for internal management review shall be prepared by August 31st, 2014. The contractor shall also provide coordination support for EPA with the principal investigator at Ohio State University.

Task 3.3: Boquerón

The contractor submitted a draft report of the Boquerón QMRA on July 2, 2014. Additional funds are provided so the contractor can assist EPA in preparing a manuscript suitable for publication in a peer reviewed journal based on the content of the draft report. The contractor shall prepare a draft manuscript by August 31, 2014 for internal management review, incorporate management comments, and prepare a final version for submission to a journal.

Task 4: Relative QMRA refinement

Tasks 4.1 and 4.2: Evaluating source and receptor locations and fecal mixtures QMRA

Additional funds are provided to maintain the ongoing collaborative effort between HECD and ORD-Athens in the area of incorporating fate and transport modeling within the QMRA framework for the purposes of estimating human health risks from recreational exposures. The contractor shall assist the WACOR with evaluating how to include this capability in the context of deriving water quality standards.

Task 4.1 is considered to require a low, but ongoing level of effort during the period of performance.

Additional funds are provided to support the finalization of the fecal mixtures QMRA manuscript that was submitted for publication earlier this year. That document is currently undergoing peer review. The contractor shall assist the WACOR in addressing peer review comments and preparing a final version of the manuscript suitable for publication.

Task 7: Chicago Area Waterways (CAWS) QMRA

Additional funds are provided so the contractor can support the WACOR by preparing technical and non-technical briefing materials on the revised CAWS QMRA. Additionally, there may be a need to conduct follow up QMRA analysis incorporating additional information on pathogen levels, updated dose-response information, etc. The contractor shall prepare draft and final versions of reports that discuss any additional analyses.

**Performance Work Statement
ICF Contract EP-C-11-005
Work Assignment #3-07 (Carryover)**

Title: Children's risks from fecal contamination in recreational water

Work Assignment Manager: John Ravenscroft (Mail Code 4304T)
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Alternate WAM:
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E-mail: akhter.shamima@epa.gov

Period of Performance: January 1, 2014 through December 31, 2014

****Note:** No CBI data will be needed in the course of this work assignment.

Contractor SOW: 3.1, 3.3, 3.6

Goal: The overall goal of this Performance Work Statement (PWS) is to examine multiple lines of evidence (Center for Disease Control (CDC) Recreational Water Illness outbreak data, risk assessment analyses and epidemiological data) to evaluate the potential that children have disproportionate risks of waterborne illness from recreational water contact.

Objectives:

1. Produce a comprehensive report for internal EPA evaluation detailing the known health information for children's waterborne illnesses from recreational water exposure. The report shall demonstrate an evaluation of the scientific literature, risk analysis (e.g., QMRA) and observational results (e.g., National Epidemiological and Environmental Assessment of Recreational Water (NEEAR) study reports).
2. Produce a draft and final report for external scientific peer review based on the information covered in objective 1.
3. Produce communications materials to accompany reports including: a 1 to 2 page

nontechnical synopsis, a technical summary document written in non-academic style for a non-scientific audience, a 'questions and answers' (Q&As) document covering areas of potential inquiry from nontechnical and technical audiences (both internal and external), and others as determined by the EPA WAM via technical direction.

Background: A growing body of scientific knowledge has demonstrated that children may suffer disproportionately from environmental health risks and safety risks. These risks occur because 1) children's neurological, immunological, digestive, and other bodily systems are still developing; 2) children eat more food, drink more fluids, and breathe more air in proportion to their body weight than adults; 4) children's size and weight may diminish their protection from standard safety features; and 5) children's behavior patterns may make them more susceptible to accidents because they are less able to protect themselves.

The importance of identifying and assessing risks to children was made in Executive Order 13045: Protection of Children from Environmental Health Risks and Safety Risk¹, which states:

"to the extent permitted by law and appropriate, and consistent with the agency's mission, each Federal agency:

(a) shall make it a high priority to identify and assess environmental health risks and safety risks that may disproportionately affect children; and (b) shall ensure that its policies, programs, activities, and standards address disproportionate risks to children that result from environmental health risks or safety risks.

1-102. Each independent regulatory agency is encouraged to participate in the implementation of this order and comply with its provisions."

The U.S. Environmental Protection Agency (EPA)'s Policy on Evaluating Risks to Children² :

"considers the risks to infants and children consistently and explicitly as a part of risk assessments generated during its decision making process, including the setting of standards to protect public health and the environment. To the degree permitted by available data in each case, the Agency will develop a separate assessment of risks to infants and children or state clearly why this is not done - for example, a demonstration that infants and children are not expected to be exposed to the stressor under examination."

The US EPA's Office of Children's Health Protection³ conducts research and supports

¹ Executive Order 13045: Protection of Children from Environmental Health Risks and Safety Risks. http://yosemite.epa.gov/ochp/ochpweb.nsf/content/whatwe_executiv.htm

² Policy on Evaluating Health Risks to Children. <http://www.epa.gov/osa/spc/pdfs/memohlth.pdf>

risk assessments to assess children's risks and susceptibility to environmental contaminants (chemicals, toxins, air pollutants). However, it not clear whether children suffer disproportionate exposures and health outcomes as a result of exposure to pathogens such as found in recreational surface waters. Few epidemiological data and quantitative risk assessments have explored children's risks from microbial contaminants found in water, limiting the ability to determine if children experience different responses to waterborne fecal indicators and pathogens, or develop illness rates as a result of recreational water contact in the United States. Risks in children have specifically not been explored separately, but they are included as part of the general populations in most epidemiological studies.

Under the auspices of the Clean Water Act, the Agency regulates recreational water, and sets numeric indicator bacteria criteria (*Escherichia coli*, Enterococci) in surface (ambient) waters used for the purpose of recreational water contact. EPA issued new CWA 304(a) recreational ambient water quality criteria in December 2012. The science underpinned the new criteria describes human health effects and water quality studies conducted in waters impacted primarily by human sources of fecal contamination. EPA would like to better understand the risks posed to children associated with recreational exposures. This PWS covers efforts to develop and disseminate the current understanding in this area.

Task Knowledge and Skills Required: The Contractor shall have expertise in preparing the materials associated with this work assignment and be knowledgeable with the various fields of discipline discussed. The Contractor shall also be proficient in R programming and other relevant statistical tools. The Contractor shall have practical experience in environmental microbiology, epidemiology, and statistical methods and analysis and have advanced credentials in statistics or environmental engineering. The Contractor shall be familiar with the different programs under the CWA, use of water quality monitoring, determination of human exposure to environmental contaminant sources, and gastrointestinal (or other) disease endpoints, applications of epidemiological data, and other factors associated with needs in recreational water quality and CWA 304(a) criteria development.

The Contractor shall also be able to communicate the study outcomes and recreational outbreak data to a non-technical audience.

Quality Assurance: The tasks in this PWS require the use of secondary data/analyses and fall under the scope of the approved contract-level QAPP. Consistent with the Agency's quality assurance (QA) requirements, the contractor must assure the quality and analyses of the secondary data and other data collected to be used under this PWS.

The Contractor shall discuss with the EPA WAM if any of the specific work assignment tasks are not readily covered under the approved QAPP. Any additional quality assurance requirements must be addressed in the work plan and monthly progress reports

³ The Office of Children's Health Protection.

http://yosemite.epa.gov/ochp/ochpweb.nsf/content/whatwe_executiv.htm

and, if needed, be covered by a WA-specific QAPP supplement, which must be approved by the EPA before activities covered by the additional QA language begin under this PWS.

Performance Work Statement (PWS): The scope in this PWS will fall under the following task areas:

Task 1: *Work Plan and monthly progress reports (MPR)*

Task Area 1.1. Work Plan

The contractor shall develop a work plan to address all tasks in this work assignment. The work plan shall include a schedule, staffing plan, level of effort (LOE), and cost estimate for each task, the contractor's key assumptions on which staffing plan and budget are based, and qualifications of proposed staff. If a subcontractor(s) is proposed and subcontractors are outside the metropolitan DC area, the contractor shall include information on plans to manage work and contract costs. All P levels, hours and total dollars for each task will be provided and costs greater than \$100.00 shall be itemized in detail. The contractor shall provide their job number with all invoices to facilitate their expediency.

Task Area 1.2. Monthly Progress Reports

This task also includes monthly progress and financial reports. The monthly progress report shall indicate, in a separate QA section, whether significant QA issues have been identified and how they are being resolved. Monthly financial reports must include a table with the invoiced LOE and costs delineated by the tasks in this WA. The Contractor shall provide the EPA WAM with weekly updates detailing progress. That updates shall be provided every Friday via email.

Travel: No contractor travel outside of the Washington, D.C. metro area is anticipated for this task.

Task Area 1.3. Information Quality Guidelines

The Contractor shall ensure the products developed under this PWS comply with the EPA Information Quality Guidelines and shall complete the Checklist for Influential Information as needed for each deliverable from this work assignment as they may be used in Agency decision-making and/or will be publicly available documents. The EPA WAM will provide the checklist to the Contractor. The Contractor shall provide a memorandum describing how the planned product(s) developed meet EPA's Information Quality Guidelines checklist. As part of that memo, the Contractor shall document the quality assurance procedures it used in developing the deliverables under this Work Assignment. The Contractor shall provide the memo at the time it delivers the Final Report under Task 2.1. As requested by the EPA WAM, the Contractor shall have a teleconference with the EPA WAM to discuss the Guidelines and the Contractor's role in completing the checklist.

Task Area 2: Project Reports

Task Area 2.1. Preparation of EPA report detailing results

The Contractor prepared and submitted a draft report for EPA technical review under this Task in the previous contract year detailing the information collected and analyzed for the evaluation of human health risks to children from recreational exposure to fecal contamination. The report was under review at the close of the previous contract year.

The Contractor shall revise the report based on the comments submitted by the EPA WAM and discuss options for addressing the comments with the EPA WAM once the Contractor has had a chance to review them. The Contractor shall also prepare effective communication materials to accompany the draft report for use in internal and eventually external communication efforts (see Task 3).

The report may undergo multiple edits and the Contractor shall respond to EPA WAM comments. This document will need to be formatted as requested by the EPA WAM. The Contractor shall incorporate comments on any draft deliverables from the EPA WAM. Also, the Contractor shall update information in the report as needed to capture any developments related to ongoing studies. The report shall be compliant with Section 508 of the Rehabilitation Act when finalized and submitted (see <http://www.epa.gov/accessibility/index.htm>).

Task Area 2.2. Preparation of Report of External Scientific Peer Review

The Contractor shall prepare and submit a version of the final report based on the deliverable under Task 2.1 that would be suitable for external scientific peer review. This task is subsequent to task 2.1. The Contractor shall submit a draft to the EPA WAM for Agency clearance. When all Agency comments have been addressed, that version may be submitted for peer review. The venue for the peer review is currently undetermined. The Contractor shall address peer reviewer comments in conjunction with the EPA WAM. This document will need to be formatted for publication as directed by the EPA WAM.

Travel: No contractor travel outside of the Washington, D.C. metro area is anticipated for this task.

Task Area 3: Communication materials

As specified in the above methodology section, the Contractor shall prepare, in conjunction with the EPA WAM, materials to assist in communicating the complex technical aspects of the project results to both non-technical and technical (but not academic) audiences (both internal and external to the Agency). These materials will most likely consist of synopses, executive summaries, Q&As, presentation slides, etc. and each may be aimed at a particular audience or tailored for the communication need. The Contractor shall coordinate with the EPA WAM on the scope and nature of these materials for specific audiences.

Task Area 4: *General Project Support*

The Contractor shall, based on technical direction given by the EPA WAM, provide support in preparing interim project update and/or other materials for internal and external audiences. These may include, but are not limited to, short briefing documents and PowerPoint presentations. The contractor may also be directed to participate in and/or conduct briefings and/or present at meetings. It is estimated that this task should not require more than 5 – 10 % of the total LOE allotted to this work assignment.

One of the outcomes of the project planning meeting detailed in Task 2.1 may be the identification of data or analysis gaps, particularly in regards to the QMRA analysis. For example, the finalized analysis of the NEEAR marine data was not completed at the time of the conduct of the QMRA under B-04, task 6. Although the final analysis of that data did not show a significant difference in illness response between children 12 and under and the general population, using this combined dataset may be helpful for the discussion of the QMRA portion of the deliverables under tasks 2.1 and 2.2. Should such analyses be identified as important based on the outcome of the project planning meeting, the EPA WAM will provide technical direction to ICF.

The Contractor shall plan on attending one presentation at EPA HQ at the draft report stage to discuss findings. All appropriate clearances and approvals required by Agency policy in support of any and all meetings shall be obtained by the EPA PO as needed and provided to the Contracting Officer. Work under meeting-related activities and expenses shall not occur until this approval is obtained and provided by the PO.

Task No.	Milestones/Deliverable*	Schedule
1	1.1 Workplan	Within 15 business days of receipt of WA
1	1.3 Information Quality Guidelines	Submitted with final deliverables
2	*2.1 Draft report for EPA review	Draft submitted
2	2.1 Respond to EPA reviewer comments	Within 2 weeks of receiving EPA comments
2	2.1 Submit final report to EPA	Within 2 weeks of addressing comments
2	2.2 Submit draft report for EPA review	TBD based on outcome of Task 2.1
2	2.2 Respond to EPA reviewer comments	Within 2 weeks of receiving EPA comments
2	2.2 Submit final report to EPA for peer review clearance	Within 2 weeks of addressing comments
3	Prepare risk communication presentation materials for technical and non-technical audiences	TBD by technical direction
4	General project support	TBD by technical direction

* Report was on schedule to be submitted to EPA by the end of previous contract year when this work assignment was being prepared. The milestone was included here to provide a starting point for Task 2 activities.

General Requirements of the Work Assignment and Schedule:

Due Dates: The Contractor shall provide due dates that are mutually acceptable with the EPA WAM. The Contractor shall notify the EPA WAM in advance, if a due date will not be met and request a revised date.

Delays: The Contractor shall make every effort to ensure there are no Contractor-caused delays. If a delay is inevitable, it is the Contractor's responsibility to notify the EPA WAM at the first sign of said delay. A revised schedule will then be worked out.

Draft Documents: The Contractor may be required to submit draft documents. Draft documents shall be prepared in an electronic format compatible with current Microsoft products. EPA WAM will provide comments on draft submissions prior to submission of final documents.

Final Documents: The Contractor shall submit final documents both electronically and in hardcopy to EPA WAM.

Attachment 1

QAPP REQUIREMENTS FOR PROJECTS USING SECONDARY DATA

A secondary data project involves the gathering and/or use of existing environmental data for purposes other than those for which they were originally collected. These secondary data may be obtained from many sources, including literature, industry surveys, compilations from computerized databases and information systems, and computerized or mathematical models of environmental processes. For these projects, a QAPP shall be prepared to include the requirements identified below. If primary data will also be generated as part of the project, then the information below can be incorporated into the associated QAPP to address the secondary data. The following requirements should be addressed as applicable.

SECTION 1.0 PROJECT OBJECTIVES, ORGANIZATION, AND RESPONSIBILITIES

- 1.1 The purpose of study shall be clearly stated.
- 1.2 Project objectives shall be clearly stated.
- 1.3 The secondary data needed to satisfy the project objectives shall be identified. Requirements relating to the type of data, the age of data, geographical representation, temporal representation, and technological representation, as applicable, shall be specified.
- 1.4 The planned approach for evaluating project objectives, including formulas, units, definitions of terms, and statistical analysis, if applicable, shall be included.
- 1.5 Responsibilities of all project participants shall be identified, meaning that key personnel and their organizations shall be identified, along with the designation of responsibilities for planning, coordination, data gathering, data analysis, report preparation, and quality assurance, as applicable.

SECTION 2.0 SOURCES OF SECONDARY DATA

- 2.1 The source(s) of the secondary data must be specified.
- 2.2 The rationale for selecting the source(s) identified shall be discussed.
- 2.3 The sources of the secondary data will be identified in any project deliverable.

SECTION 3.0 QUALITY OF SECONDARY DATA

- 3.1 Quality requirements of the secondary data must be specified. These requirements must be appropriate for their intended use. Accuracy, precision, representativeness, completeness, and comparability need to be addressed, if applicable. (If appropriate, a related QAPP containing this information can be referenced.)

- 3.2 The procedures for determining the quality of the secondary data shall be described.
- 3.3 If no quality requirements exist, this shall be stated in the QAPP. If no quality requirements exist or if the quality of the secondary data will not be evaluated by EPA, the QAPP shall require that a disclaimer be added to any project deliverable to indicate that the quality of the secondary data has not been evaluated by EPA for this specific application. The wording for the disclaimer shall be defined.

SECTION 4.0 DATA REPORTING, DATA REDUCTION, AND DATA VALIDATION

- 4.1 Data reduction procedures specific to the project shall be described, including calculations and equations.
- 4.2 The data validation procedures used to ensure the reporting of accurate project data shall be described.
- 4.3 The expected product document that will be prepared shall be specified (*e.g.*, journal article, final report, *etc.*).

References

CDC Rec Water Outbreaks:

Alphabetical index of Water-Related Health Data:

http://www.cdc.gov/healthywater/statistics/surveillance/health_data.html

CDC Healthy Swimming Webpage: <http://www.cdc.gov/healthywater/swimming/data/>

Epidemiological studies:

"High Sensitivity of Children to Swimming-Associated Gastrointestinal Illness Results Using a Rapid Assay of Recreational Water Quality" Timothy J. Wade, Rebecca L. Calderon, Kristen P. Brenner, Elizabeth Sams, Michael Beach, Richard Haugland, Larry Wymer, and Alfred P. Dufour (Epidemiology 2008;19: 375–383)
http://journals.lww.com/epidem/Abstract/2008/05000/High_Sensitivity_of_Children_to.8.aspx

Marine Studies (P1, 2):

"Rapidly measured indicators of recreational water quality and swimming-associated illness at marine beaches: A prospective cohort study" Timothy J Wade , Elizabeth Sams, Kristen P Brenner , Rich Haugland , Eunice Chern , Michael Beach , Larry Wymer, Clifford C Rankin , David Love , Quanlin Li , Rachel Noble and Alfred P Dufour - Environmental Health 2010, 9:66doi:10.1186/1476-069X-9-66
Published: 31 October 2010

- Table S2: Adjusted Odds Ratios for illness risk among swimmers for a 1 log₁₀ Increase in indicator density. Children age 10 and under.

<http://www.ehjournal.net/imedia/3968942414721357/supp2.pdf>

Epidemiological study in marine waters impacted by urban runoff in a temperate region (CD 5(a)):

"Report on 2009 National Epidemiologic and Environmental Assessment of Recreational Water Epidemiology Studies" Timothy J Wade , Elizabeth A Sams, Rich Haugland, Kristen P Brenner, Quanlin Li, Larry Wymer, Marirosa Molina, Kevin Oshima and Alfred P Dufour. US Environmental Protection Agency, Office of Research and Development; 2010. USEPA Report Number: EPA/600/R-10/168.

- Table 4.5, 4.6: Water exposures among children
- Tables 4.8-4.12: Incidence of illness among children
- Table 4.39, 4.42, 4.56, 4.57,
- Figure 5.16: Incidence of illness among children with regard to measures of water quality.

<http://water.epa.gov/scitech/swguidance/waterquality/standards/criteria/health/recreation/index.cfm>

Epidemiological study in a tropical region (CD 5(b)):

"Report on 2009 National Epidemiologic and Environmental Assessment of

Recreational Water Epidemiology Studies" Timothy J Wade , Elizabeth A Sams, Rich Haugland, Kristen P Brenner, Quanlin Li, Larry Wymer, Marirosa Molina, Kevin Oshima and Alfred P Dufour. US Environmental Protection Agency, Office of Research and Development; 2010. USEPA Report Number: EPA/600/R-10/168.

Wade, T. J., R. L. Calderon, et al. (2006). "Rapidly measured indicators of recreational water quality are predictive of swimming-associated gastrointestinal illness." *Environ Health Perspect* 114(1): 24-8.

Wade, T. J., N. Pai, et al. (2003). "Do U.S. Environmental Protection Agency Water Quality Guidelines for Recreational Waters Prevent Gastrointestinal Illness? A Systematic Review and Meta-analysis." *Environmental Health Perspectives* 111(8): 1102-1109.

Colford, J. M., Jr., T. J. Wade, et al. (2007). "Water Quality Indicators and the Risk of Illness at Beaches With Nonpoint Sources of Fecal Contamination." *Epidemiology* 18(1): 27-35.

Fleisher, J. M., F. Jones, et al. (1993). "Water and non-water-related risk factors for gastroenteritis among bathers exposed to sewage-contaminated marine waters." *International Journal of Epidemiology* 22(4): 698-708.

Fleisher, J. M., D. Kay, et al. (1996). "Marine waters contaminated with domestic sewage: nonenteric illnesses associated with bather exposure in the United Kingdom." *Am J Public Health* 86(9): 1228-34.

Kay, D., J. M. Fleisher, et al. (1994). "Predicting likelihood of gastroenteritis from sea bathing: results from randomised exposure." *Lancet* 344(8927): 905-9.

Wiedenmann, A., P. Kruger, et al. (2006). "A randomized controlled trial assessing infectious disease risks from bathing in fresh recreational waters in relation to the concentration of *Escherichia coli*, intestinal enterococci, *Clostridium perfringens*, and somatic coliphages." *Environ Health Perspect* 114(2): 228-36.

Kay, D., N. Ashbolt, et al. (2006). "Reply to comments on "Derivation of numerical values for the World Health Organization guidelines for recreational waters"." *Water Res* 40(9): 1921-5.

Kay, D., J. Bartram, et al. (2004). "Derivation of numerical values for the World Health Organization guidelines for recreational waters." *Water Res* 38(5): 1296-304.

A description of EPI-BATHE can be found:
<http://www.aber.ac.uk/iges/research/epibathe/favorite.htm>

EPAUnited States Environmental Protection Agency
Washington, DC 20460**Work Assignment**

Work Assignment Number

3-08



Other



Amendment Number:

Contract Number

EP-C-11-005

Contract Period 01/01/2011 To 12/31/2014

Base

Option Period Number 3

Title of Work Assignment/SF Site Name

AWQC for Pathogens

Contractor

ICF INCORPORATED, L.L.C.

Specify Section and paragraph of Contract SOW

3.1, 3.3, 3.4, 3.6

Purpose:



Work Assignment



Work Assignment Close-Out



Work Assignment Amendment



Incremental Funding



Work Plan Approval

Period of Performance

From 01/01/2014 To 12/31/2014

Comments:



Superfund

Accounting and Appropriations Data



Non-Superfund

SFO

(Max 2)



Note: To report additional accounting and appropriations data use EPA Form 1900-89A.

Line	DCN (Max 6)	Budget/FY (Max 4)	Appropriation Code (Max 6)	Budget Org/Code (Max 7)	Program Element (Max 9)	Object Class (Max 4)	Amount (Dollars)	(Cents)	Site/Project (Max 8)	Cost Org/Code (Max 7)
1										
2										
3										
4										
5										

Authorized Work Assignment Ceiling

Contract Period:

01/01/2011 To 12/31/2014

Cost/Fee:

LOE:

This Action:

Total:

Work Plan / Cost Estimate Approvals

Contractor WP Dated:

Cost/Fee:

LOE:

Cumulative Approved:

Cost/Fee:

LOE:

Work Assignment Manager Name Sharon Nappier

Branch/Mail Code:

Phone Number 202-566-0740

FAX Number:

(Signature)

(Date)

Project Officer Name Shirley Harrison

Branch/Mail Code:

Phone Number: 202-566-1107

FAX Number:

(Signature)

(Date)

Other Agency Official Name Shirley Harrison

Branch/Mail Code:

Phone Number: 202-566-1107

FAX Number:

(Signature)

(Date)

Contracting Official Name Sandra Stargardt-Licis

Branch/Mail Code:

Phone Number: 513-487-2006

FAX Number:

(Signature)

(Date)

**PERFORMANCE WORK STATEMENT
ICF CONTRACT EP-C-11-005
WORK ASSIGNMENT #3-08**

Title: Activities to support the development of Ambient Water Quality Criteria for Pathogens

Work Assignment Manager: Sharon Nappier (Mail Code 4304T)
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E-mail: nappier.sharon@epa.gov

Alternate WAM: John Ravenscroft (Mail Code 4304T)
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Phone (202) 566-1101
E-mail: ravenscroft.john@epa.gov

Period of Performance: January 1, 2014 thru December 31, 2014

Contractor SOW: 3.1, 3.3, 3.4, 3.6

****Note:** No CBI data will be needed in the course of this work assignment.

Background:

Human health ambient water quality criteria (AWQC) are numeric values limiting the amount of chemical or microbial agents present in our nation's waters. Human health criteria are developed under Section 304(a) of the Clean Water Act of 1972 and are designed to protect human health. Water quality criteria are developed by assessing the relationship between pollutants and their effect on human health and the environment. These criteria are used by states and Indian tribes to establish water quality standards and ultimately provide a basis for controlling discharges or releases of pollutants.

EPA has published AWQC for bacteria. Historically EPA has based the bacteria criteria on fecal indicator bacteria (FIB). These organisms do not generally cause human illness themselves (that is, they are not human pathogens); rather, they are indicators of fecal contamination and therefore indicators of the potential presence of human pathogenic organisms.

The EPA is now interested in creating AQWC for viruses. EPA believes that these virus criteria must be scientifically sound, implementable for broad CWA purposes, and provide for improved public health protection.

Quality Assurance:

The tasks in this work assignment (WA) require the use of secondary data/analyses and fall under the scope of the approved contract-level QAPP. Consistent with the Agency's quality assurance (QA) requirements, the contractor must assure the quality and analyses of the secondary data and other data collected to be used under this work assignment.

The contractor shall discuss with the EPA WAM if any of the specific work assignment tasks are not readily covered under the approved contract-level QAPP. Any additional quality assurance requirements must be addressed in the work plan and monthly progress reports and, if needed, be covered by a WA-specific QAPP supplement, which must be approved by the EPA WAM before activities covered by the additional QA language begin under this work assignment.

Performance Work Statement (PWS): The contractor shall perform the following tasks:

Task 1: Work plan and monthly progress reports

The contractor shall develop a detail work plan and cost estimate for each task outlined in this work assignment. The plan should contain, but not limited to, work-flowchart, elaborate schedule (task-wise), staffing plan and qualifications of proposed staff, budget for each task and level of effort (LOE). Prior to the submission of the work plan, the contractor shall consult with the EPA WAM via conference call to mitigate any potential issues that need clarifications. The contractor shall include information on plans to manage work and control contract costs. All P levels, hours and total dollars for each task will be provided and costs greater than \$100.00 shall be itemized in detail. The contractor shall provide their job number with all invoices to facilitate their expediency.

Task 1.2 Monthly Progress Reports

This task also includes monthly progress and financial reports. The monthly progress report shall indicate, in a separate QA section, whether significant QA issues have been identified and how they are being resolved. Monthly financial reports must include a table with the invoice LOE and costs' broken out by the tasks in this WA.

Task 1.3 Information Quality Guidelines

The contractor shall ensure the products developed under this work assignment comply with the EPA Information Quality Guidelines and shall complete the Checklist for Influential Information as needed for each deliverable from this work assignment as they may be used in Agency decision-making and/or will be publicly available documents. The EPA WAM will provide the checklist to the contractor. The contractor shall provide a memorandum describing how the planned product(s) developed meet

EPA's Information Quality Guidelines checklist. As part of that memo, the contractor shall document the quality assurance procedures it used in developing the deliverables under this Work Assignment. The contractor shall provide the memo at the time it delivers the Final Summary Report. As requested by the EPA WAM, the contractor shall have a teleconference with the EPA WAM to discuss the Guidelines and the contractor's role in completing the checklist.

Task 2 - Re-evaluate, Update, and Finalize the *Methodology for Deriving Microbial AWQC for Recreational Designated Uses for the Protection of Human Health*

In 2006, EPA drafted the recommended *Methodology for Deriving Microbial AWQC for Recreational Designated Uses for the Protection of Human Health*. The Microbial Methodology is guidance for scientific human health assessments used by EPA to develop, publish, and revise, recommended criteria for water quality accurately reflecting the latest scientific knowledge. The recommended criteria would serve states' and tribes' needs in their development of water quality standards under §303(c) of the CWA.

The contractor shall finalize the *Methodology for Deriving Microbial AWQC for Recreational Designated Uses for the Protection of Human Health* for publication. The most recent document underwent External Peer Review in 2006. However, the contractor shall update and re-evaluate the document to reflect the most recent draft *Microbiological Risk Assessment (MRA) Tools, Methods, and Approaches for Water Media* and the current scientific literature. Process steps for re-evaluating, updating, and finalizing the document will be provided through Technical Direction (TD).

TASK 3 – Literature Reviews

Task Area 3.1 Bacteriophage Literature Review

This task is a continuation of previous efforts under WA 2-08 to conduct a bacteriophage literature review to identify important research that support the development of future bacteriophage criteria. In addition to 304(a) criteria, the review should address the potential usefulness of bacteriophages as indicators in biosolids and in shellfish waters. EPA anticipates there will be several internal reviews of the document. The contractor shall assist in incorporating comments and edits and deliver a final literature review product. The contractor shall make the final document 508 compliant.

Task Area 3.2 Norovirus: Human Health Assessment

This task is a continuation of previous efforts under WA 2-08 to conduct EPA Human Health Assessment document for noroviruses and in the process identify important research that will support the development of future virus criteria. EPA anticipates there will be several internal reviews of the Human Health Assessment. The contractor shall assist in incorporating comments and edits and deliver a final Human Health Assessment product. The contractor shall make the final document 508 compliant.

Task Area 3.3 Adenovirus: Human Health Assessment

This task is a continuation of previous efforts under WA 2-08 to conduct EPA Human Health Assessment document for adenoviruses and in the process identify important research that will support the development of future virus criteria. EPA anticipates there will be several internal reviews of the Human Health Assessment. The contractor shall assist in incorporating comments and edits and deliver a final Human Health Assessment product. The contractor shall make the final document 508 compliant.

TASK 4 – Ambient Water Quality Criteria Bacteriophages and other Viruses

Task Area 4.1 Scope of the Criteria Documents

This task will require the contractor to assist scoping the AWQC for Viruses for recreational designated uses. Viruses of immediate interest include, but are not limited to, bacteriophage, norovirus, and enterovirus. EPA is considering one criterion document for bacteriophages and another for pathogenic viruses, such as enteroviruses and noroviruses. The contractor shall assist in drafting an outline of pathogen criteria for viral indicators and pathogenic viruses and identifying the needs of the criterion documents.

Task Area 4.2 Derivation of the Criteria Values

Drawing on the draft *Microbiological Risk Assessment (MRA) Tools, Methods, and Approaches for Water Media*, the *Methodology for Deriving Microbial AWQC for Recreational Designated Uses for the Protection of Human Health*, and any other materials EPA deems appropriate, the contractor shall develop AWQC values for the viruses of interest. Specific viruses and the order of importance will be provided through Technical Direction (TD).

Task Area 4.3 Develop Criterion Document Drafts

The contractor shall provide draft documents of the AWQC for viruses. Again, specific viruses and the order of importance will be provided through Technical Direction. This task will be an ongoing effort for the period of performance of this work assignment and a series of Drafts are expected.

Task Area 4.4 Prepare/submit Final AWQC Criteria for Bacteriophage and other Viruses

The contractor shall prepare and submit a Final RWQC document. This document will need to be 508 Compliant and formatted as directed by the EPA WAM.

Task Area 4.5 Prepare briefing materials and other supporting documents pertaining to the Virus Criteria documents

Briefing materials and other supporting documents will be needed during the Criteria development process. The contractor shall aid in the development of any materials or presentations for these purposes.

Travel: No contractor travel outside of the Washington, D.C. metro area is anticipated for this task.

Task Area 5 - General Project Support

The contractor shall, based on technical direction given by the EPA WAM, provide support in preparing interim project update and other materials for internal and external audiences. These may include, but are not limited to, short briefing documents and PowerPoint presentations. The contractor may be requested to participate in and/or conduct briefings. A weekly update call with the EPA WAM will be required for this work assignment, as needed.

Some meetings may require contractor support and/or attendance for note-taking, presentations, and meeting preparation materials. Details on travel dates and locations will be provided by the EPA WAM through technical direction, as further information becomes available.

Travel: Travel may be needed as deemed necessary by the EPA WAM. No contractor travel outside of the Washington, D.C. metro area is required.

Task No.	Deliverable	Schedule
1	1.1 Work Plan	Due <u>15</u> calendar days after receipt of WA
2	2.0 Re-evaluate, update, and finalize the <i>Methodology for Deriving Microbial Ambient Water Quality Criteria for Recreational Designated Uses for the Protection of Human Health</i>	TBD
3	3.1 Bacteriophage Literature Review - DRAFT	Two weeks after receipt draft from EPA.
3	3.1 Bacteriophage Literature Review - FINAL for Peer-Review	Two weeks after receipt draft from EPA.
3	3.2 Norovirus: Human Health Assessment - DRAFT	Two weeks after receipt draft from EPA
3	3.2 Norovirus: Human Health Assessment - FINAL for Peer-Review	Two weeks after receipt draft from EPA
4	4.1 Scope of the Criteria documents	TBD
4	4.2 Derivation of the Criteria Values	TBD
4	4.3 Develop Criteria Document Drafts	TBD
4	4.4 Submit Final AWQC Criteria for Review	TBD
4	4.5 Prepare briefing materials and other supporting documents	TBD
5	5.0 General Project Support	TBD

Quality Assurance: Tasks 2-4 in this work assignment require the use of secondary data. An approved project-specific QAPP has already been approved, under the previous WA B-08. The project specific quality assurance requirements must be addressed in the work plan and monthly progress reports as specified under Task 1 and should follow the attachment titled, QAPP Requirements for projects using secondary data.

Knowledge and Skills Required: The contractor shall have expertise in preparing the aforementioned materials and be knowledgeable with the various fields of discipline discussed in this work assignment. The contractor shall have practical experience in conducting microbial risk assessments and have advanced credentials in environmental microbiology and/or environmental engineering. The contractor shall be familiar with the use of fecal indicator organisms, microbiological analytical methods (including molecular techniques), water monitoring applications of epidemiological data, determination of human exposure to environmental contaminant sources, and gastrointestinal disease endpoints.

General Requirements of the Work Assignment and Schedule:

Due Dates: The contractor shall provide due dates that are mutually acceptable with the EPA WAM. The contractor shall notify the EPA WAM in advance, if a due date will not be met and request a revised date.

Delays: The contractor shall make every effort to ensure there are no Contractor-caused delays. If a delay is inevitable, it is the contractor's responsibility to notify the EPA WAM at the first sign of said delay. A revised schedule will then be worked out.

Draft Documents: The contractor may be required to submit draft documents. Draft documents shall be prepared in an electronic format compatible with current Microsoft products. EPA WAM will provide comments on draft submissions prior to submission of final documents.

Final Documents: The contractor shall submit final documents both electronically and in hardcopy to EPA WAM.

MEETINGS, CONFERENCES, TRAINING EVENTS, AWARD CEREMONIES AND RECEPTIONS:

All appropriate clearances and approvals required by Agency policy in support of any and all conference related activities and expenses, including support of meetings, conferences, training events, award ceremonies and receptions, shall be obtained by the EPA PO as needed and provided to the Contracting Officer. Work under conference related activities and expenses shall not occur until this approval is obtained and provided by the EPA PO.

Attachment 1

QAPP REQUIREMENTS FOR PROJECTS USING SECONDARY DATA

A secondary data project involves the gathering and/or use of existing environmental data for purposes other than those for which they were originally collected. These secondary data may be obtained from many sources, including literature, industry surveys, compilations from computerized databases and information systems, and computerized or mathematical models of environmental processes. For these projects, a QAPP shall be prepared to include the requirements identified below. If primary data will also be generated as part of the project, then the information below can be incorporated into the associated QAPP to address the secondary data. The following requirements should be addressed as applicable.

SECTION 1.0, PROJECT OBJECTIVES, ORGANIZATION, AND RESPONSIBILITIES

- 1.1 The purpose of study shall be clearly stated.
- 1.2 Project objectives shall be clearly stated.
- 1.3 The secondary data needed to satisfy the project objectives shall be identified. Requirements relating to the type of data, the age of data, geographical representation, temporal representation, and technological representation, as applicable, shall be specified.
- 1.4 The planned approach for evaluating project objectives, including formulas, units, definitions of terms, ~~statistical~~ data analysis (i.e. statistical analysis & any other types of data analysis), and assumptions/recommendations based on the data analysis, if applicable, shall be included.
- 1.5 Responsibilities of all project participants shall be identified, meaning that key personnel and their organizations shall be identified, along with the designation of responsibilities for planning, coordination, data gathering, data analysis, report preparation, and quality assurance, as applicable.

SECTION 2.0, SOURCES OF SECONDARY DATA

- 2.1 The source(s) of the secondary data must be specified.
- 2.2 The rationale for selecting the source(s) identified shall be discussed.
- 2.3 The sources of the secondary data will be identified in any project deliverable.

SECTION 3.0, QUALITY OF SECONDARY DATA

- 3.1 Quality requirements of the secondary data must be specified. These requirements must be appropriate for their intended use. Accuracy, precision, representativeness, completeness, and comparability need to be addressed, if applicable. (If appropriate, a related QAPP containing this information can be referenced.)
- 3.2 The procedures for determining the quality of the secondary data shall be described.
- 3.3 If no quality requirements exist, this shall be stated in the QAPP. If no quality requirements exist or if the quality of the secondary data will not be evaluated by EPA, the QAPP shall require that a disclaimer be added to any project deliverable to indicate that the quality of the secondary data has not been evaluated by EPA for this specific application. The wording for the disclaimer shall be defined.

SECTION 4.0, DATA REPORTING, DATA REDUCTION, AND DATA VALIDATION

- 4.1 Data reduction procedures specific to the project shall be described, including calculations and equations.
- 4.2 The data validation procedures used to ensure the reporting of accurate project data shall be described.
- 4.3 The expected product document that will be prepared shall be specified (*e.g.*, journal article, final report, *etc.*).

EPA United States Environmental Protection Agency Washington, DC 20460 Work Assignment		Work Assignment Number 3-08								
		<input type="checkbox"/> Other <input checked="" type="checkbox"/> Amendment Number: 000001								
Contract Number EP-C-11-005	Contract Period 01/01/2013 To 12/31/2013	Title of Work Assignment/SF Site Name								
	Base Option Period Number 3	AWQC for Pathogens								
Contractor ICF Incorporated, L.L.C.		Specify Section and paragraph of Contract SOW								
Purpose: <input type="checkbox"/> Work Assignment <input type="checkbox"/> Work Assignment Close-Out <input checked="" type="checkbox"/> Work Assignment Amendment <input type="checkbox"/> Incremental Funding <input type="checkbox"/> Work Plan Approval		Period of Performance From 01/01/2014 To 12/31/2014								
Comments: ICF Workplan 3-08 is fully funded at the contractor's cost estimate of \$397,110; 3,048 LOE hours										
<input type="checkbox"/> Superfund		Accounting and Appropriations Data								
		<input checked="" type="checkbox"/> Non-Superfund								
SFO <input type="checkbox"/> (Max 2)		Note: To report additional accounting and appropriations data use EPA Form 1900-69A.								
Line	DCN (Max 6)	Budget/FY (Max 4)	Appropriation Code (Max 6)	Budget Org/Code (Max 7)	Program Element (Max 9)	Object Class (Max 4)	Amount (Dollars)	(Cents)	Site/Project (Max 8)	Cost Org/Code (Max 7)
1										
2										
3										
4										
5										
Authorized Work Assignment Ceiling										
Contract Period:		Cost/Fee:		LOE:						
01/01/2013 To 12/31/2013										
This Action:										
Total:										
Work Plan / Cost Estimate Approvals										
Contractor WP Dated:		Cost/Fee:		LOE:						
Cumulative Approved:		Cost/Fee:		LOE:						
Work Assignment Manager Name Sharon Nappier							Branch/Mail Code:			
							Phone Number 202-566-0740			
							FAX Number:			
(Signature) _____ (Date) _____										
Project Officer Name Shirley Harrison							Branch/Mail Code:			
							Phone Number: 202-566-1107			
							FAX Number:			
(Signature) _____ (Date) _____										
Other Agency Official Name							Branch/Mail Code:			
							Phone Number:			
							FAX Number:			
(Signature) _____ (Date) _____										
Contracting Official Name Sandra Stargardt-Licis							Branch/Mail Code:			
							Phone Number: 513-487-2006			
							FAX Number:			
(Signature) _____ (Date) _____										

EPA United States Environmental Protection Agency Washington, DC 20460 Work Assignment		Work Assignment Number 3-09 <input type="checkbox"/> Other <input type="checkbox"/> Amendment Number:								
Contract Number EP-C-11-005	Contract Period 01/01/2011 To 12/31/2014 Base Option Period Number 3	Title of Work Assignment/SF Site Name Human Health Assessment: Crypt								
Contractor ICF INCORPORATED, L.L.C.		Specify Section and paragraph of Contract SOW 2.2, 3.1.6, 3.1.8								
Purpose: <input checked="" type="checkbox"/> Work Assignment <input type="checkbox"/> Work Assignment Close-Out <input type="checkbox"/> Work Assignment Amendment <input type="checkbox"/> Incremental Funding <input type="checkbox"/> Work Plan Approval		Period of Performance From 01/01/2014 To 12/31/2014								
Comments:										
<input type="checkbox"/> Superfund Accounting and Appropriations Data <input checked="" type="checkbox"/> Non-Superfund										
SFO (Max 2) <input type="checkbox"/> Note: To report additional accounting and appropriations data use EPA Form 1900-69A.										
Line	DCN (Max 6)	Budget/FY (Max 4)	Appropriation Code (Max 6)	Budget Org/Code (Max 7)	Program Element (Max 9)	Object Class (Max 4)	Amount (Dollars)	(Cents)	Site/Project (Max 8)	Cost Org/Code (Max 7)
1										
2										
3										
4										
5										
Authorized Work Assignment Ceiling										
Contract Period: 01/01/2011 To 12/31/2014		Cost/Fee:				LOE:				
This Action:										
Total:										
Work Plan / Cost Estimate Approvals										
Contractor WP Dated:		Cost/Fee:				LOE:				
Cumulative Approved:		Cost/Fee:				LOE:				
Work Assignment Manager Name Shamima Akhter						Branch/Mail Code:				
_____ (Signature) (Date)						Phone Number 202-566-0000				
						FAX Number:				
Project Officer Name Shirley Harrison						Branch/Mail Code:				
_____ (Signature) (Date)						Phone Number: 202-566-1107				
						FAX Number:				
Other Agency Official Name Shirley Harrison						Branch/Mail Code:				
_____ (Signature) (Date)						Phone Number: 202-566-1107				
						FAX Number:				
Contracting Official Name Sandra Stargardt-Licis						Branch/Mail Code:				
_____ (Signature) (Date)						Phone Number: 513-487-2006				
						FAX Number:				

PERFORMANCE WORK STATEMENT
ICF CONTRACT EP-C-11-005
WORK ASSIGNMENT # 3-09 (Carryover)

Title: Human Health Assessment: *Cryptosporidium* and *Giardia* in drinking and ambient water

Work Assignment Manager: Shamima Akhter (Mail Code 4304T)
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Office of Water, Office of Science and Technology
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Phone (202) 566-1341
E-mail: akhter.shamima@epa.gov

Alternate WAM: John Ravenscroft (Mail Code 4304T)
Health and Ecological Criteria Division
Office of Water, Office of Science and Technology
1200 Pennsylvania Ave, N.W.
Washington, DC 20460
Phone (202) 566-1101
E-mail: ravenscroft.john@epa.gov

Period of Performance: January 1, 2014 through December 31, 2014

Contractor SOW: 2.2, 3.1.6, and 3.1.8

Background:

The mission of the U.S. Environmental Protection Agency's (EPA) Office of Water is to protect public health and the environment from adverse effects of pollutants (e.g., toxic chemicals and microbial pathogens) in ambient water, drinking water, wastewater, sewage sludge and sediments. The Safe Drinking Water Act (SDWA) requires the EPA to regulate disease-causing organisms (pathogens) and toxic chemicals in drinking water.

The Safe Drinking Water Act requires the U.S. Environmental Protection Agency (EPA) to publish regulations to control disease-causing organisms (pathogens) and hazardous chemicals in drinking water. One of the regulations published by EPA to control pathogens is known as the Surface Water Treatment Rule (54 FR 27486; June 29, 1989). The purpose of the Long Term 2 (LT2) rule is to reduce illness linked with the contaminant *Cryptosporidium*, *Giardia* and other disease-causing microorganisms in drinking water. Under the LT 2 Rule, *Cryptosporidium* oocysts at or below 0.075 oocysts/liter are considered the maximum value under which conventional drinking water treatment is expected to be capable of providing protection of consumers drinking up to 1.2 liters of water per day. Under the Safe Drinking Water Act's Surface Water Treatment Rule (further referred to as the Rule) *Giardia* cyst Maximum Contaminant Level Goal (MCLG) levels are set at "0" for treated water. In order to meet this

requirement, *Giardia* cyst removal by conventional drinking water treatment must be able to reduce cyst levels by 3 orders of magnitude (3 logs) from source waters to insure protection of consumers drinking up to 2.0 liters of water per day.

Cryptosporidium is a significant concern in drinking water because it contaminates surface waters used as drinking water sources, it is resistant to chlorine and other disinfectants, and it has caused waterborne disease outbreaks. Consuming water with *Cryptosporidium*, a contaminant in drinking water sources, can cause gastrointestinal illness (e.g., diarrhea, vomiting, cramps) and other health risks, which may be severe in people with weakened immune systems (e.g., infants and the elderly) and sometimes fatal in people with severely compromised immune systems (e.g., cancer and AIDS patients).

Cryptosporidium oocysts are common and widespread in ambient water and can persist for months in this environment. The dose that can infect humans is low, and a number of waterborne disease outbreaks caused by this protozoan have occurred in the U.S., most notably in Milwaukee, where an estimated 400,000 people became ill. The healthy people recover within several weeks after becoming ill, but illness may persist and contribute to death in those whose immune systems have been seriously weakened (e.g., AIDS patients). Drugs effective in preventing or controlling this disease are not yet available. The public health concern is worsened by the resistance of *Cryptosporidium* to water disinfection practices by chlorination, although oocysts can be inactivated by ozone and ultraviolet irradiation. However, a well-operated water filtration system is capable of removing at least 99 of 100 *Cryptosporidium* oocysts in the water. Monitoring for this organism in water is currently difficult and expensive.

The purpose of these documents is to serve as informal technical guidance to assist Federal, state, and local officials responsible for protecting public health when emergency spills or contamination situations occur.

Quality Assurance:

The tasks in this work assignment (WA) require the use of secondary data/analyses and fall under the scope of the approved contract-level QAPP. Consistent with the Agency's quality assurance (QA) requirements, the contractor must assure the quality and analyses of the secondary data and other data collected to be used under this work assignment.

The Contractor shall discuss with the EPA WAM if any of the specific work assignment tasks are not readily covered under the approved QAPP. Any additional quality assurance requirements must be addressed in the work plan and monthly progress reports and, if needed, be covered by a WA-specific QAPP supplement, which must be approved by the EPA WAM before activities covered by the additional QA language begin under this work assignment.

Performance Work Statement (PWS):

Task 1: Work plan and monthly progress reports

Task 1.1 Work Plan

The contractor shall develop a detail work plan and cost estimate for each task outlined in this work assignment. The plan should contain, but not limited to, work-flowchart, elaborate schedule (task-wise), staffing plan and qualifications of proposed staff, budget for each task and level of effort (LOE). Prior to the submission of the work plan, the contractor shall consult with the WAM via conference call to mitigate any potential issues that need clarifications. The contractor shall include information on plans to manage work and control contract costs. All P levels, hours and total dollars for each task will be provided and costs greater than \$100.00 shall be itemized in detail. The contractor shall provide their job number with all invoices to facilitate their expediency.

This task also includes monthly progress and financial reports. The monthly progress report shall indicate, in a separate QA section, whether significant QA issues have been identified and how they are being resolved. Monthly financial reports must include a table with the invoice LOE and costs' broken out by the tasks in this WA.

Task 1.2 Information Quality Guidelines

The Contractor shall ensure the products developed under this work assignment comply with the EPA Information Quality Guidelines and shall complete the Checklist for Influential Information as needed for each deliverable from this work assignment as they may be used in Agency decision-making and/or will be publicly available documents. The EPA WAM will provide the checklist to the Contractor. The Contractor shall provide a memorandum describing how the planned product(s) developed meet EPA's Information Quality Guidelines checklist. As part of that memo, the Contractor shall document the quality assurance procedures it used in developing the deliverables under this Work Assignment. The Contractor shall provide the memo at the time it delivers the Final Summary Report. The Contractor shall have a teleconference with the EPA WAM to discuss the Guidelines and the Contractor's role in completing the checklist.

Task 2: Develop Health Assessment document: *Cryptosporidium*

2.5 Submit revised report

The contractor shall revise and finalize the health assessment document based upon EPA WAM's review comments.

2.6 Communication piece

The contractor shall provide a brief communication (1- 3 pages) which will aid in briefing EPA managers and senior managers. The communication piece shall be written in plain English language for non-technical people and the relevant scientific studies shall be included as an attachment.

2.7 Response to the Peer Reviewer comments

Upon receipt of the EPA's external expert peer-review of the Contractor's Final Written Report, the EPA WAM will provide the Contractor with the recommended edits and modifications. The Contractor shall address all recommended peer-review modifications. Changes will be documented in a separate report for the record to describe how the peer-review comments were incorporated into the final report.

2.8 Incorporate Peer Reviewer comments to the documents

The contractor shall incorporate all recommended edits and modifications to the documents. The Contractor shall provide the revised final report (and documented changes to the report) to the EPA WAM for review.

2.9 Submit Final Report

Upon the EPA WAM's approval, the Contractor shall send the final revised peer-reviewed report in Microsoft Word, version 2003 or higher, to the EPA WAM

Task 3: Develop Health Assessment document: *Giardia*

3.2 Develop analysis plan and conduct exposure and dose response analysis

3.3 Submit draft report of initial findings

The contractor shall prepare a draft *Giardia* health assessment document for EPA WAM's review. The contractor shall insure that all factors that were applied to the health assessment are stated and are transparent throughout the document. It is EPA's concern that contractor shall include a list of references used for this task. In addition, contractor shall also include a list of unused references along with clear justification for not using them. The contractor shall coordinate with the EPA WAM as inclusion or exclusion of any references to the draft document.

3.4 Incorporate EPA comments and additional studies

The EPA WAM will periodically search diverse data bases for potential new information and will provide to the contractor. The contractor shall incorporate any additional studies into revisions to draft report upon receipt from EPA WAM. It is the goal of the EPA WAM to gather as many examples as possible and available to help inform the policy development process. The contractor shall also incorporate EPA WAM's review comments to the document.

3.5 Submit revised report

The contractor shall revise and finalize the health assessment document based upon EPA WAM's review comments.

3.6 Communication piece

The contractor shall provide a brief communication (1- 3 pages) which will aid in briefing manager and senior managers. The communication piece shall be written in plain English language for non-technical people and the relevant scientific studies shall be included as an attachment.

3.7 Response to the Peer Reviewer comments

Upon receipt of the EPA's external expert peer-review of the Contractor's Final Written Report, the EPA WAM will provide the Contractor with the recommended edits and modifications. The Contractor shall address all recommended peer-review modifications. Changes will be documented in a separate report for the record to describe how the peer-review comments were incorporated into the final report.

3.8 Incorporate Peer Reviewer comments to the documents

The contractor shall incorporate all recommended edits and modifications to the documents. The Contractor shall provide the revised final report (and documented changes to the report) to the EPA WAM for review.

3.9 Submit Final Report

Upon the EPA WAM's approval, the Contractor shall send the final revised peer-reviewed report in Microsoft Word, version 2003 or higher, to the EPA WAM

Period of Performance/Milestones: It is the Contractor's responsibility to coordinate with EPA WAM while conducting these tasks.

Task	Milestone	Date due
1	1.1 Work Plan	Due 15 calendar days after receipt of WA
1	Kick-off meeting with EPA WAM	1 week after WP approval
2	2.5 Submit revised report	2 months after WP approval
2	2.6 Communication Piece	TBD
2	2.7 Response to the Peer Reviewer comments	TBD
2	2.8 Incorporate Peer Reviewer comments	TBD
2	2.9 Submit final report	TBD
3	3.3 Submit draft report of initial findings	1 month after WP approval
3	3.4 Incorporate EPA comments and additional studies, if identified	6 weeks after WP approval
3	3.5 Submit revised report	2 months after WP approval
3	3.6 Communication Piece	TBD
3	3.7 Response to the Peer Reviewer comments	TBD
3	3.8 Incorporate Peer Reviewer comments	TBD
3	3.9 Submit final report	TBD

Knowledge and Skills Required: The Contractor shall have expertise in preparing the aforementioned materials and be knowledgeable with the various fields of discipline discussed in this PWS. The contractor shall be an accomplished microbial risk assessor with experience in environmental media, especially water. The contractor shall have knowledge and experience with the *Cryptosporidium* and *Giardia* spp. protozoa in water and water/wastewater treatment/disinfection effectiveness. The contractor shall be experienced in evaluation of data bases, statistics, and modeling regarding human exposure, dose response and health effects for application in microbial risk assessments.

General Requirements of the Work Assignment and Schedule:

Due Dates: The Contractor shall provide due dates that are mutually acceptable with the EPA WAM. The Contractor shall notify the EPA WAM in advance, if a due date will not be met and request a revised date.

Delays: The Contractor shall make every effort to ensure there are no Contractor-caused delays. If a delay is inevitable, it is the Contractor's responsibility to notify the EPA WAM at the first sign of said delay. A revised schedule will then be worked out.

Draft Documents: The Contractor may be required to submit draft documents. Draft documents shall be prepared in an electronic format compatible with current Microsoft products. EPA WAM will provide comments on draft submissions prior to submission of final documents.

Final Documents: The Contractor shall submit final documents both electronically and in hardcopy to EPA WAM.

Final Documents: The Contractor shall revise and incorporate all EPA's comments and submit final documents both electronically and in hardcopy (Microsoft version 2003 or higher) to EPA WAM. The Agency may decide to publish the report on the web. If this occurs, the report will need to be 508 compliant and the COR will provide appropriate technical direction.

Final Peer Reviewed Document: Upon receipt of the EPA's external expert peer-review of the Contractor's Final Written Report, the EPA WAM will provide the Contractor with the recommended edits and modifications. The Contractor shall address all recommended peer-review modifications. Changes will be documented in a separate report for the record to describe how the peer-review comments were incorporated into the final report. The Contractor shall provide the revised final report (and documented changes to the report) to the EPA WAM for review. Upon the EPA WAM's approval, the Contractor shall send the final revised peer-reviewed report in Microsoft Word, version 2003 or higher, to the EPA WAM.

MEETINGS, CONFERENCES, TRAINING EVENTS, AWARD CEREMONIES AND RECEPTIONS:

All appropriate clearances and approvals required by Agency policy in support of any and all conference related activities and expenses, including support of meetings, conferences, training events, award ceremonies and receptions, shall be obtained by the EPA PO as needed and provided to the Contracting Officer. Work under conference related activities and expenses shall not occur until this approval is obtained and provided by the EPA PO.

EPAUnited States Environmental Protection Agency
Washington, DC 20460**Work Assignment**

Work Assignment Number

3-10

☐ Other ☐ Amendment Number:

Contract Number

EP-C-11-005

Contract Period 01/01/2011 To 12/31/2014

Base

Option Period Number 3

Title of Work Assignment/SF Site Name

Secondary Contact WQS

Contractor

ICF INCORPORATED, L.L.C.

Specify Section and paragraph of Contract SOW

3.1, 3.3, 3.4

Purpose:



Work Assignment



Work Assignment Close-Out



Work Assignment Amendment



Incremental Funding



Work Plan Approval

Period of Performance

From 01/01/2014 To 12/31/2014

Comments:



Superfund

Accounting and Appropriations Data



Non-Superfund

SFO
(Max 2)

Note: To report additional accounting and appropriations data use EPA Form 1900-69A.

Line	DCN (Max 6)	Budget/FY (Max 4)	Appropriation Code (Max 6)	Budget Org/Code (Max 7)	Program Element (Max 9)	Object Class (Max 4)	Amount (Dollars)	(Cents)	Site/Project (Max 8)	Cost Org/Code (Max 7)
1										
2										
3										
4										
5										

Authorized Work Assignment Ceiling

Contract Period:

01/01/2011 To 12/31/2014

Cost/Fee:

LOE:

This Action:

Total:

Work Plan / Cost Estimate Approvals

Contractor WP Dated:

Cost/Fee:

LOE:

Cumulative Approved:

Cost/Fee:

LOE:

Work Assignment Manager Name Sharon Nappier

Branch/Mail Code:

Phone Number 202-566-0740

FAX Number:

(Signature)

(Date)

Project Officer Name Shirley Harrison

Branch/Mail Code:

Phone Number: 202-566-1107

FAX Number:

(Signature)

(Date)

Other Agency Official Name Shirley Harrison

Branch/Mail Code:

Phone Number: 202-566-1107

FAX Number:

(Signature)

(Date)

Contracting Official Name Sandra Stargardt-Licis

Branch/Mail Code:

Phone Number: 513-487-2006

FAX Number:

(Signature)

(Date)

**PERFORMANCE WORK STATEMENT
ICF CONTRACT EP-C-11-005
WORK ASSIGNMENT #3-10 (Carryover)**

Title: Secondary Contact Water Quality Standards for Pathogens

Work Assignment Manager: Gary Russo (Mail Code 4305T)
Standards and Health Protection Division
Office of Water, Office of Science and Technology
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Washington, DC 20460
Phone (202) 566-1335
E-mail: russo.gary@epa.gov

Alternate WAM: Sharon Nappier (Mail Code 4304T)
Health and Ecological Criteria Division
Office of Water, Office of Science and Technology
1200 Pennsylvania Avenue, N.W.
Washington, DC 20460
Phone (202) 566-0740
E-mail: nappier.sharon@epa.gov

Period of Performance: January 1, 2014 through December 31, 2014

Contractor SOW: 3.1, 3.3, and 3.4

CBI: No confidential business information will be needed for this work assignment.

Background:

An effort is currently underway to revise EPA's bacteriological water quality criteria under section 304(a) of the Clean Water Act (CWA). Both the current and proposed revised criteria primarily address water quality standards for "primary contact" recreational uses and do not significantly address "secondary contact" recreational uses. Primary contact recreation is typically defined as water-based recreational activities that could be expected to result in the ingestion of or immersion in water such as swimming, water skiing, or surfing. Secondary contact recreation is typically defined as water-based recreational activities where contact with the water is either incidental or accidental, and the probability of ingesting appreciable quantities of water is minimal.

Current EPA policy allows States, tribes and territories to adopt bacteriological criteria for secondary contact uses that are less stringent than criteria for primary contact uses.

The justification for less stringent secondary contact criteria is based on the assumption that secondary contact activities are associated with exposure to fewer pathogenic organisms. It is believed that a higher concentration of pathogens in water is counterbalanced by a lower potential exposure to those pathogens, resulting in the same risk of illness in secondary recreational activities as risks associated with primary recreational activities. However, the potential for pathogen exposure during different recreational activities is not well characterized, and there is currently no scientific consensus on whether or not they are in fact associated with different risks of illness (differential risk).

Although there is a body of scientific literature addressing the risk of illness associated with various water-based recreational activities, the relationships between different activities, water quality, and health risks are not well understood. The wide ranges of existing studies often have ambiguous results or support conflicting conclusions. Such ambiguity and/or disagreement may be due to a variety of reasons, including differences in the questions being addressed, differences, biases and/or flaws in the way the studies were designed or conducted, differences in interpretation of the study results, or simply due to chance.

The purpose of this Performance Work Statement (PWS) is to examine the evidence for or against differential risk by conducting a systematic review. A systematic review is a specific type of literature review that focuses on a specific research question and tries to identify, appraise, select and synthesize all high quality research and evidence relevant to that question. The overall goal of a systematic review is to provide an objective and transparent synthesis of research results that minimizes bias. The systematic review from this PWS will provide an up-to-date, state-of-the-art evaluation of the current scientific knowledge of the health risks associated with different water-based recreational activities in water contaminated by fecal material. The results and conclusions of the systematic review will be used to inform EPA policies and decisions associated with recreational water quality standards for the protection of public health.

Performance Work Statement (PWS):

The scope of work in this PWS will fall under the following tasks:

Task 1 – Work plan, quality assurance, and monthly progress reports

Task Area 1.2 Work plan

The contractor shall develop a work plan to address all tasks in the performance work statement (PWS). The work plan shall include a schedule, staffing plan, level of effort (LOE), and cost estimate for each task, the contractor's key assumptions on which staffing plan and budget are based, and qualifications of proposed staff. If one or more

subcontractor(s) are proposed and they are outside the metropolitan DC area, the contractor shall include information on plans to manage work and contract costs. The number and professional level of hours charged and total dollars for each task will be provided. Other costs greater than \$100.00 shall be itemized.

- Deliverable – Work plan.
- Deadline – fifteen (15) calendar days after receipt of work assignment

Task Area 1.3. Quality assurance

Upon completion of the systematic review, the contractor shall complete the EPA Office of Water Information Quality Guidelines checklist and supporting narrative. See Attachment 2.

- Deliverable – Completed Information Quality Guidelines checklist
- Deadline – seven (7) calendar days following completion of the systematic review.

Task Area 1.4 Monthly Progress Reports

The contractor shall provide progress and financial reports to the EPA WAM each month. The contractor shall also provide any information related to the execution of this PWS when ever requested by the EPA WAM. The progress report shall indicate, in a separate QA/QC section, whether QA/QC issues have been identified and how they will be resolved. If significant QA/QC issues are encountered, the contractor shall contact the EPA WAM immediately to discuss the issue. If work ceases because of QA/QC issues, the contractor shall not resume work until receiving written approval from the EPA WAM. Monthly financial reports shall at minimum include a table with the invoice LOE and costs for each task and task area in this PWS.

Task 2 – Develop a systematic review of the scientific evidence related to differential risk of illness with different water-based recreational activities.

Task Area 2.3 Revise the review protocol in response to possible peer review comments

The systematic review protocol has been peer-reviewed. The contractor has already received written technical direction to revise the review protocol in response to the peer review comments. After the systematic review protocol has been approved by the EPA WAM, the EPA WAM may decide that a peer review of the protocol by independent experts outside the EPA is needed. Should the EPA WAM decide that an external peer review is necessary, the contractor shall provide assistance and advice in developing the charge for the peer review and in interpreting the peer review comments. Should the EPA WAM decide that the review protocol needs to be revised in response to an external peer

review, the contractor shall revise the review protocol in accordance with the technical direction provided by the EPA WAM. The contractor shall adhere to the same standards of quality as when initially developing the review protocol as specified in Task Area 2.2. Revisions shall be performed in close collaboration with the EPA WAM and other EPA staff designated by the EPA WAM. The contractor shall not begin the review itself until the review protocol has been finalized and the contractor receives written instructions to do so by the EPA WAM.

- Deliverable – Revised review protocol.
- Deadline – thirty (30) days after receiving peer review comments.

Task Area 2.4 Conduct the systematic review

Upon completion of the final review protocol and receiving written instructions by the EPA WAM, the contractor shall conduct the systematic review as specified in the review protocol. During the screening phase, the contractor shall inform the EPA WAM of the results of initial screening process before beginning full screening of potentially relevant papers. When performing the systematic review, the contractor shall strictly adhere to the review protocol and shall not deviate from it without explicit written permission from the EPA WAM.

Although one objective of the systematic review is to strictly adhere to the review protocol once finalized, modification of the finalized review protocol may be appropriate in some circumstances such as when a clearer understanding of the review question(s) becomes apparent, or when initial screening of papers using the specified eligibility criteria results in too few or too many papers. If, after initial consideration of the studies being reviewed, it becomes apparent that a change in direction may be required, the contractor shall immediately cease review activities and notify the EPA WAM. If the EPA WAM determines that protocol modifications are needed, the contractor shall modify the protocol in consultation with the EPA WAM. The contractor shall not resume review activities until the final modified review protocol is reviewed and approved by the EPA WAM and the contractor receives written instructions to resume review activities. Protocol modifications shall be clearly and fully documented in a protocol addendum and in the final report of the review findings. This documentation shall include a clear description of the differences between the initial and amended protocol, and the implications of the modification on the review findings. **Under no circumstances shall the protocol be modified or the review altered because of awareness of the results of individual studies.**

Throughout the review process, the contractor shall provide progress reports to the EPA WAM. The contractor shall also provide electronic copies of all documents that were screened during the study selection process or used in the systematic review. A database

of complete document citations along with the file name of the electronic copy shall also be provided to the EPA WAM as an Endnote database or another electronic format that can easily be imported into Endnote.

At the conclusion of the systematic review, the contractor shall provide a brief report outlining the results of the review. The report shall be well written, organized thoughtfully, concise, grammatically correct, have no spelling errors, academically rigorous, contain high quality tables and figures if needed, and formatted so that it can serve as the foundation for developing a manuscript to be submitted for publication in a high-quality peer-reviewed journal.

- Deliverable – Report on review results.
- Deadline – ninety (90) days after receiving instructions from the EPA WAM to begin the systematic review.

Task Area 2.5 Develop one or more manuscripts for publication of the systematic review.

At the conclusion of the systematic review, the contractor shall develop one or more manuscripts for publication of the systematic review. The manuscript(s) shall be developed in close consultation with the EPA WAM with the goal of publishing the systematic review in a high quality, high impact, peer-reviewed journal. The manuscript(s) shall be organized thoughtfully, written concisely, grammatically correct, academically rigorous, contain high quality tables and figures when appropriate, and formatted for the journal being targeted. The manuscript(s) shall be developed in a way that allows reformatting for submission to other journals if the need arises. The contractor shall revise the manuscript(s) as instructed via technical direction by the EPA WAM in response to reviewer comments, and develop written responses to reviewer comments for submission to the journal editor. The contractor shall conform to the same standards of quality when revising the manuscript(s) as specified above for initially developing the manuscript(s). The contractor shall also prepare the Information Quality Guidelines Checklist necessary for products that EPA disseminates to the public under EPA's Information Quality Guidelines.

- Deliverable – Draft manuscript.
- Deadline – thirty (30) days after conclusion of the systematic review.

Task Area 3 - General Project Support

Task Area 3.1 Prepare briefing materials and other supporting documents pertaining to the systematic review

Briefing materials and other supporting documents will be needed during the systematic

review development process and after the review is published. The contractor shall aid in the development of any materials or presentations for these purposes. This may include but is not limited to preparing interim project updates and other materials for internal and external audiences as requested by the EPA WAM, briefing documents, PowerPoint presentations, and other supporting documents as needed. The contractor may be requested by the EPA WAM to participate in and/or conduct briefings or participate in seminars or talks related to the systematic review.

- Deliverable – Requested materials and supporting documents.
- Deadline – As agreed upon by the EPA WAM and contractor

Task Area 3.2 Support options development and analyses for potential changes to EPA policies related to bacteriological water quality standards.

As the results and conclusions of the systematic review become clear, the EPA may want to consider alternative policies related to bacteriological water quality standards. The contractor shall aid in the development of potential alternative policy options. These activities may include, but are not limited to, performing additional research and analysis of existing scientific data and information, analysis of the potential public health outcomes resulting from policy modifications, and the analysis of water quality standard implementation implications associated with the adoption of alternative bacteriological water quality standards. The contractor may be requested to participate in and/or conduct briefings or other presentations related to this work.

- Deliverable – Requested materials.
- Deadline – As agreed upon by the EPA WAM and contractor

Travel:

Travel may be needed as deemed necessary by the EPA WAM. No contractor travel outside of the Washington, D.C. metro area is required.

Conferences:

All appropriate clearances and approvals required by Agency policy in support of any and all conference related activities and expenses, including support of meetings, conferences, training events, award ceremonies and receptions, shall be obtained by the EPA WAM as needed and provided to the Contracting Officer. Work under conference related activities and expenses shall not occur until this approval is obtained and provided by the EPA WAM.

Knowledge and Skills Required:

The contractor shall have the necessary scientific knowledge and expertise to develop the

aforementioned materials in this PWS that are high quality and use state-of-the-art methods. Specifically, the contractor shall have experience designing, performing, and publishing primary scientific research evaluating the health effects of environmental pollution, as well as experience designing, performing, and publishing systematic- and meta-analyses of such studies. The contractor shall have expertise in epidemiological studies that evaluate microbiological water pollution using fecal indicator organisms. The contractor shall be proficient in advanced state-of-the-art statistical methods typically used to analyze epidemiological studies and perform meta-analyses. The contractor should also be competent in analytical methods used to monitor microbial water pollution (including molecular techniques), the determination of human exposure to environmental contaminant sources, and disease endpoints related to microbial exposure through contact with water.

General Requirements of the Work Assignment and Schedule:

Due Dates

The contractor shall mutually acceptable due dates with EPA WAM. The contractor shall notify the EPA WAM in advance, if a due date will not be met and negotiate a mutually acceptable revised due date.

Delays

The contractor shall provide sufficient qualified man-power to ensure there are no avoidable delays. If a delay outside the control of the contractor is unavoidable, the contractor shall immediately notify the EPA WAM and negotiate a mutually acceptable revised schedule.

Draft Documents

The contractor shall submit draft or interim work products requested by the EPA WAM. Draft or interim work products shall be prepared in an electronic format compatible with Microsoft Office 2007 or Endnote X. The EPA WAM will provide the contractor with comments on draft work products in electronic format. Work products shall be deemed draft until designated as final by the EPA WAM.

Final Documents

The contractor shall submit final documents electronically to the EPA WAM.

MEETINGS, CONFERENCES, TRAINING EVENTS, AWARD CEREMONIES AND RECEPTIONS:

All appropriate clearances and approvals required by Agency policy in support of any and all conference related activities and expenses, including support of meetings,

conferences, training events, award ceremonies and receptions, shall be obtained by the EPA PO as needed and provided to the Contracting Officer. Work under conference related activities and expenses shall not occur until this approval is obtained and provided by the EPA PO.

ATTACHMENT 1

QAPP Requirement for Projects Using Secondary Data

A project involving secondary data gathers and uses existing data for purposes other than those for which they may have been originally collected. These secondary data may be obtained from many sources including literature, industry, computerized databases and information systems, and computerized or mathematical models of environmental processes. For projects that use secondary data, a QAPP shall be prepared that include the requirements identified below. If primary data will also be generated as part of the project, then the information below can be incorporated into the associated QAPP to address the secondary data. The following requirements should be addressed as applicable.

Section 1. Project Objectives, Organization, and Responsibilities

- 1.1 The purpose of study shall be clearly stated.
- 1.2 Project objectives shall be clearly stated.
- 1.3 The secondary data needed to satisfy the project objectives shall be identified. Requirements relating to the type of data, the age of data, geographical representation, temporal representation, and technological representation, as applicable, shall be specified.
- 1.4 The planned approach for evaluating project objectives, including formulas, units, definitions of terms, and statistical or other types of data analysis. Assumptions and or recommendations based on the data analysis shall also be included if applicable.
- 1.5 Responsibilities of all project participants shall be identified, meaning that key personnel and their organizations shall be identified, along with the designation of responsibilities for planning, coordination, data gathering, data analysis, report preparation, and quality assurance, as applicable.

Section 2. Sources of Secondary Data

- 2.1 The source(s) of the secondary data must be specified.
- 2.2 The rationale for selecting the source(s) identified shall be discussed.
- 2.3 The sources of the secondary data will be identified in any project deliverable.

Section 3. Quality of Secondary Data

- 3.1 Quality requirements of the secondary data must be specified. These requirements must be appropriate for their intended use. Accuracy, precision, representativeness, completeness, and comparability need to be addressed, if

applicable. (If appropriate, a related QAPP containing this information can be referenced.)

- 3.2 The procedures for determining the quality of the secondary data shall be described.
- 3.3 If no quality requirements exist, this shall be stated in the QAPP. If no quality requirements exist or if the quality of the secondary data will not be evaluated by EPA, the QAPP shall require that a disclaimer be added to any project deliverable to indicate that the quality of the secondary data has not been evaluated by EPA for this specific application. The wording for the disclaimer shall be defined.

Section 4. Data Reporting, Data Reduction, and Data Validation

- 4.1 Data reduction procedures specific to the project shall be described, including calculations and equations.
- 4.2 The data validation procedures used to ensure the reporting of accurate project data shall be described.
- 4.3 The expected product document that will be prepared shall be specified (*e.g.*, journal article, final report, *etc.*).

EPA United States Environmental Protection Agency Washington, DC 20460 Work Assignment		Work Assignment Number 3-11								
		<input type="checkbox"/> Other <input type="checkbox"/> Amendment Number:								
Contract Number EP-C-11-005		Contract Period 01/01/2011 To 12/31/2014 Base Option Period Number 3								
Title of Work Assignment/SF Site Name TSM for Alt Health Realtionshi										
Contractor ICF INCORPORATED, L.L.C.		Specify Section and paragraph of Contract SOW 3.1, 3.3, 3.6								
Purpose: <input checked="" type="checkbox"/> Work Assignment <input type="checkbox"/> Work Assignment Close-Out <input type="checkbox"/> Work Assignment Amendment <input type="checkbox"/> Incremental Funding <input type="checkbox"/> Work Plan Approval		Period of Performance From 01/24/2014 To 12/31/2014								
Comments:										
<div style="display: flex; justify-content: space-between;"> <input type="checkbox"/> Superfund Accounting and Appropriations Data <input checked="" type="checkbox"/> Non-Superfund </div>										
SFO (Max 2) <input type="checkbox"/> Note: To report additional accounting and appropriations date use EPA Form 1900-69A.										
Line	DCN (Max 6)	Budget/FY (Max 4)	Appropriation Code (Max 6)	Budget Org/Code (Max 7)	Program Element (Max 9)	Object Class (Max 4)	Amount (Dollars)	(Cents)	Site/Project (Max 8)	Cost Org/Code (Max 7)
1										
2										
3										
4										
5										
Authorized Work Assignment Ceiling										
Contract Period:		Cost/Fee:		LOE:						
01/01/2011 To 12/31/2014										
This Action:										
Total:										
Work Plan / Cost Estimate Approvals										
Contractor WP Dated:		Cost/Fee:		LOE:						
Cumulative Approved:		Cost/Fee:		LOE:						
Work Assignment Manager Name John Ravenscroft						Branch/Mail Code:				
_____ (Signature) (Date)						Phone Number 202-566-1101				
						FAX Number:				
Project Officer Name Shirley Harrison						Branch/Mail Code:				
_____ (Signature) (Date)						Phone Number: 202-566-1107				
						FAX Number:				
Other Agency Official Name Shirley Harrison						Branch/Mail Code:				
_____ (Signature) (Date)						Phone Number: 202-566-1107				
						FAX Number:				
Contracting Official Name Sandra Stargardt-Licis						Branch/Mail Code:				
_____ (Signature) (Date)						Phone Number: 513-487-2006				
						FAX Number:				

Performance Work Statement
ICF Contract # EP-C-11-005
Work Assignment #3-11 (Carryover)

Title: Support for Developing Technical Support Materials for Deriving Site-Specific Water Quality Criteria Based on Alternative Health Relationships

Work Assignment Manager: John Ravenscroft (Mail Code 4304T)
Office of Water, Office of Science and Technology
Health and Ecological Criteria Division
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Washington, DC 20460
Phone (202) 566-1101
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Alternate WAM: Shamima Akhter (Mail Code 4304T)
Office of Science and Technology, Office of Water
Health and Ecological Criteria Division
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E-mail: akhter.shamima@epa.gov

Period of Performance: Work Assignment Issuance through December 31, 2014

****Note:** No CBI data will be needed in the course of this work assignment.

Contractor PWS: 3.1, 3.3, and 3.6

Goal: The overall goal of this work assignment is to develop implementation guidance for States and Tribes to use in developing site-specific water quality criteria based on alternative human health associations with water quality measures.

Objectives:

1. Produce a comprehensive report for internal EPA evaluation detailing the framework, process, and scientific foundation that the intended end users of this information (i.e., States, Tribes, and EPA) can utilize in developing and evaluating a site-specific water quality standards package based on an alternative human health relationship with water quality.

2. Respond to EPA and peer review comments on the report covered in Objective 1.
3. Produce a polished report in response to Objective 2 that the Agency can publish on its website
4. Produce communications materials to accompany reports including: a 1 to 2 page nontechnical synopsis, a technical summary document written in non-academic style for a non-scientific audience, a 'questions and answers' (Q&As) document covering areas of potential inquiry from nontechnical and technical audiences (both internal and external), and others as determined by the EPA WAM via technical direction.

Background: EPA recently issued new CWA 304(a) Recreational Water Quality Criteria (RWQC) at the end of 2012. The science underpinning the new criteria describes human health effects and water quality studies conducted in waters impacted primarily by human sources of fecal contamination. EPA recommended water quality criteria for fecal indicator bacteria based on the epidemiological studies conducted by EPA's Office of Research and Development (ORD). These studies were conducted at a subset of recreational waters impacted by human fecal contamination. While EPA considers these recommended criteria to be scientifically defensible and protective of the use on a national basis, the Agency recognized that certain site-specific conditions exist that would allow alternative, equally protective, criteria to be considered for Water Quality Standards. EPA clarified additional potential approaches to developing site-specific water quality criteria in Section 5 of the draft RWQC published in December 2011. These approaches focused on three main areas: 1) alternative indicators; 2) alternative sources of fecal contamination; and 3) alternative health relationships. This work assignment addresses the alternative health relationship approach.

Generally speaking, the alternative health relationship approach would consist of the development of a site-specific recreational water quality criteria derived from a human health association with water quality that differs from the one EPA has used as the basis for the nationally-applicable 2012 recommendations. EPA has committed to publishing implementation guidance, hereafter termed Technical Support Materials (TSM), for use by States and Tribes who may be interested in pursuing the development of site-specific criteria. This work assignment covers the various aspects needed to develop these TSM, including the collation and development of background and supplemental information needed for the application of this approach in the development of site-specific Water Quality Standards packages to be evaluated by EPA.

Quality Assurance: The tasks in this work assignment (WA) require the use of secondary data/analyses and fall under the scope of the approved contract-level QAPP. Consistent with the Agency's quality assurance (QA) requirements, the contractor must assure the quality and analyses of the secondary data and other data collected to be used under this work assignment.

The Contractor shall discuss with the EPA WAM if any of the specific work assignment tasks are not readily covered under the approved QAPP. Any additional quality assurance requirements must be addressed in the work plan and monthly progress reports and, if needed, be covered by a WA-specific QAPP supplement, which must be approved by the EPA before activities covered by the additional QA language begin under this work assignment.

Task 1: Work plan, monthly progress reports and quality assurance

Task 1.1: Work plan

The contractor shall develop a work plan to address all tasks in this work assignment. The work plan shall include a schedule, staffing plan, level of effort (LOE), and cost estimate for each task, the contractor's key assumptions on which staffing plan and budget are based, and qualifications of proposed staff. If a subcontractor(s) is proposed and subcontractors are outside the metropolitan DC area, the contractor shall include information on plans to manage work and contract costs. All P levels, hours and total dollars for each task will be provided and costs greater than \$100.00 shall be itemized in detail. The contractor shall provide their job number with all invoices to facilitate their expediency.

This task also includes monthly progress and financial reports. The monthly progress report shall indicate in a separate QA section, whether significant QA issues have been identified and how they are being resolved. Monthly financial reports must include a table with the invoice LOE and costs delineated by the tasks in this WA. These reports should also indicate an estimate for the next month by task and if any lagging costs are expected. EPA realizes these estimates are just approximate values and is interested in having this information for internal budgeting purposes.

Task 1.2: Information Quality Guidelines

The Contractor shall ensure the products developed under this work assignment comply with the EPA Information Quality Guidelines and shall complete the Checklist for Influential Information as needed for each deliverable from this work assignment as they may be used in Agency decision-making and/or will be publicly available documents. The EPA WAM will provide the checklist to the Contractor. The Contractor shall provide a memorandum describing how the planned product(s) developed meet EPA's Information Quality Guidelines checklist. As part of that memo, the Contractor shall document the quality assurance procedures it used in developing the deliverables under this Work Assignment. The Contractor shall provide the memo at the time it delivers the Final Summary Report. As directed by the EPA WAM, the Contractor shall have a teleconference with the EPA WAM to discuss the Guidelines and the Contractor's role in completing the checklist.

Task 2: General Project Support and Development of TSM Considering Alternative Health Relationships

EPA is planning to make available guidance to States for consideration in developing site-specific Water Quality Standards (WQS) packages utilizing alternative human health associations with water quality measures. Task 2 comprises the different facets of the guidance development project and includes project planning, communication strategies, and document preparation.

Task 2.1. Project planning and management

The Contractor shall conduct project strategic planning in conjunction with the EPA WAM. The purpose of this subtask will be to develop a comprehensive plan that includes all related tasks and deliverables in the context of the Agency timeline for publishing RWQC and implementation guidance. The plan will also describe how each task or subtask will aid EPA in meeting its goals in regards to the publication of technical support materials in support of criteria implementation and may be iterative in nature. Project management coordination between the EPA WAM and the Contractor shall occur for the duration of the work assignment. Regular periodic meetings between the EPA WAM and the Contractor shall occur once the workplan has been approved.

Task 2.2. Project communication support

The contractor shall, based on technical direction given by the EPA WAM, provide support in preparing interim project updates and other materials for internal and external audiences. These may include, but are not limited to, short briefing documents and PowerPoint presentations. The Contractor may also be directed to participate in briefings and meetings. The Contractor may also be directed to prepare reports for communication outside the EPA based on deliverables generated by tasks under this work assignment. The Contractor shall coordinate with the EPA WAM for the proper timing and need for these activities.

Interpretation and meta-analyses of epidemiological evidence are two potential technical areas that will need to be considered in the preparation of the TSM. The Contractor shall anticipate the need to discuss specific topics of a highly technical nature with ORD epidemiologists and also to convey the outcomes of such discussions to a non-technical audience.

Task 2.3: TSM document development

The purpose of this task is to develop a guide for use by States and localities for the purposes of deriving site-specific water quality criteria derived from alternative human health relationships to water quality, including information for evaluating the technical basis for the site-specific criteria. This guide should also provide information for EPA, particularly for Regional personnel who are tasked to evaluate State WQS packages. This document shall discuss a process to help States determine if a water body is eligible for the development of site-specific criteria, what information can be used to provide a line of evidence approach for demonstrating human health relationships with water quality, the differing approaches to establishing human health relationships with water quality, a comparison of site-specific health relationships to those used by EPA as a basis for the nationally recommended water quality criteria, a potential epidemiological and Quantitative Microbial Risk Assessment (QMRA) hybrid approach for demonstrating human health relationships, how to prepare a site-specific water quality standards package, and other topics as needed to be specified by the EPA WAM (and in consultation with HECD's partners in SHPD). The main goal for this deliverable is to produce guidance for use by States in developing microbial WQS that are scientifically defensible, protective of the recreational designated use, and meet EPA standards for consideration and potential approval.

This document should be clear to a potentially non-technical audience on the state of the science for epidemiology and risk assessment. For example, a good discussion will be needed for comparing results from various epidemiological studies conducted with different study designs. The discussion should include what the differences between the study designs are and what impact they have on the potential interpretation of the results, particularly in terms of comparing study results to EPA's recommendations. This type of discussion will be important for evaluating the scientific defensibility and protection of the designated use for any site-specific criteria derived from alternative study designs. The Contractor shall use examples from the peer reviewed literature, where possible, to highlight this discussion.

The draft deliverable for this task (see table below) will need to be peer reviewed by a 3rd party. The Contractor shall respond to the peer reviewer comments as directed by the EPA WAM via technical direction in preparation of the final deliverable. The final deliverable shall be Section 508 compliant as specified in the US Rehabilitation Act internet-based publications.

This task will require the Contractor to attend meetings with the EPA WAM and other staff at EPA Headquarters during the period of performance for the purposes of project updates, planning and communication.

All appropriate clearances and approvals required by Agency policy in support of any and all conference related activities and expenses, including support of meetings, conferences, training events, award ceremonies and receptions, shall be obtained by the EPA PO as needed and provided to the Contracting Officer. Work under conference related activities and expenses shall not occur until this approval is obtained and provided by the PO.

General Requirements of the Work Assignment and Schedule:

Due Dates: The Contractor shall provide due dates that are mutually acceptable with the EPA WAM. The Contractor shall notify the EPA WAM in advance, if a due date will not be met and request a revised date.

Delays: The Contractor shall make every effort to ensure there are no Contractor-caused delays. If a delay is inevitable, it is the Contractor's responsibility to notify the EPA WAM at the first sign of said delay. A revised schedule will then be worked out.

Draft Documents: The Contractor may be required to submit draft documents. Draft documents shall be prepared in an electronic format compatible with current Microsoft products. EPA WAM will provide comments on draft submissions prior to submission of final documents.

Final Documents: The Contractor shall submit final documents both electronically and in hardcopy to EPA WAM.

Task Knowledge and Skills Required: The Contractor shall have expertise in preparing the materials associated with this work assignment and be knowledgeable with the various fields of discipline discussed, including epidemiology, microbial risk assessment, biostatistics, and environmental microbiology. The Contractor shall be familiar with the different programs under the CWA, use of water quality monitoring, determination of human exposure to environmental contaminant sources, and gastrointestinal (or other) disease endpoints, applications of epidemiological data, and other factors associated with needs in recreational water quality and CWA 304(a) criteria development. The Contractor shall also be able to communicate the study outcomes and recreational outbreak data to a non-technical audience.

Milestone/Deliverable Table

Task	Task #	Milestones and Due Dates
Task 1: Work plan, monthly progress reports and quality assurance		
Workplan	1.1	Within 15 calendar days of receipt of work assignment
Information Quality Guidelines	1.2	Discuss with EAP WAM within 15 calendar days of receipt of work assignment. IQG checklists due with final deliverable (can be included with QA materials).
Task 2: General Project Support		
Project Planning and Management	2.1	Update current plan as needed. Schedule periodic meetings with EPA WAM after approval of workplan.
Project Communications Support	2.2	After the workplan approval, throughout the period of performance. Communication materials will be informed by the results and be targeted for different audiences..
Technical Support Materials	2.3	Revised Draft for internal review, mid January (communication materials included); EPA may have additional comments; quick turnaround on any comments so that the peer review can begin by mid-March, 3 rd party peer review will take approximately 90 days; Contractor shall coordinate with EPA WAM on the response to comments; Final by 6/30/14 contingent on EPA comments.

**PERFORMANCE WORK STATEMENT
ICF CONTRACT EP-C-11-005
WORK ASSIGNMENT # 3-11 Amendment 1**

Title: Support for Developing Technical Support Materials for Deriving Site-Specific Water Quality Criteria Based on Alternative Health Relationships

Work Assignment Contracting Officer Representative (WACOR): John Ravenscroft (Mail Code 4304T)
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Health and Ecological Criteria Division
U.S. Environmental Protection Agency
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Phone (202) 566-1101
E-mail: ravenscroft.john@epa.gov

Alternate WACOR: Shamima Akhter (Mail Code 4304T)
Office of Water, Office of Science and Technology
Health and Ecological Criteria Division
U.S. Environmental Protection Agency
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Period of Performance: Work Assignment Amendment Issuance through December 31, 2014

****Note:** No CBI data will be needed in the course of this work assignment.

Contractor PWS: 3.1, 3.3, and 3.6

Purpose of Amendment: The purpose of this amendment is to provide additional LOE and funding for the existing tasks. Deliverables under task 2 have necessitated additional rounds of review and editing that were not anticipated when the original work assignment was prepared. The additional LOE and funding will help to prepare useful deliverables of sufficient quality for EPA and maintain project timelines. Unless specifically mentioned, the language contained in the original work assignment still applies (e.g., Information Quality Guidelines, QA section, etc.). All deliverables and milestones remain unchanged. Additional resources are also being provided for Task 1 for the remainder of the period of performance. The contractor shall submit a cost estimate for this amendment.

EPA United States Environmental Protection Agency Washington, DC 20460						Work Assignment Number 3-12			
Work Assignment									
Contract Number EP-C-11-005		Contract Period 01/01/2011 To 12/31/2014 Base Option Period Number 3				Title of Work Assignment/SF Site Name HHealth: Legionella			
Contractor ICF Incorporated, L.L.C.				Specify Section and paragraph of Contract SOW see PWS					
Purpose:		<input checked="" type="checkbox"/> Work Assignment <input type="checkbox"/> Work Assignment Amendment <input type="checkbox"/> Work Plan Approval		<input type="checkbox"/> Work Assignment Close-Out <input type="checkbox"/> Incremental Funding		Period of Performance From 07/17/2014 To 12/31/2014			
Comments:									
<input type="checkbox"/> Superfund Accounting and Appropriations Data <input checked="" type="checkbox"/> Non-Superfund									
SFO (Max 2) <input type="checkbox"/> Note: To report additional accounting and appropriations date use EPA Form 1900-69A.									
Line	DCN (Max 6)	Budget/FY (Max 4)	Appropriation Code (Max 6)	Budget Org/Code (Max 7)	Program Element (Max 9)	Object Class (Max 4)	Amount (Dollars) (Cents)	Site/Project (Max 8)	Cost Org/Code (Max 7)
1									
2									
3									
4									
5									
Authorized Work Assignment Ceiling									
Contract Period: 01/01/2011 To 12/31/2014		Cost/Fee:		LOE:					
This Action:									
Total:									
Work Plan / Cost Estimate Approvals									
Contractor WP Dated:				Cost/Fee:		LOE:			
Cumulative Approved:				Cost/Fee:		LOE:			
Work Assignment Manager Name Shamima Akhter						Branch/Mail Code:			
						Phone Number 202-566-0000			
(Signature) _____ (Date) _____						FAX Number:			
Project Officer Name Shirley Harrison						Branch/Mail Code:			
						Phone Number: 202-566-1107			
(Signature) _____ (Date) _____						FAX Number:			
Other Agency Official Name Shirley Harrison						Branch/Mail Code:			
						Phone Number: 202-566-1107			
(Signature) _____ (Date) _____						FAX Number:			
Contracting Official Name Sandra Stargardt-Licis						Branch/Mail Code:			
						Phone Number: 513-487-2006			
(Signature) _____ (Date) _____						FAX Number:			

**PERFORMANCE WORK STATEMENT
ICF CONTRACT EP-C-11-005
WORK ASSIGNMENT # 3-12**

Title: Human Health Assessment: *Legionella* in drinking and ambient water

Work Assignment Contracting Officer Representative (WACOR):

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Alternate WACOR:

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Contractor PWS: 2.2, 3.1.6, and 3.1.8

Period of Performance: Issuance through December 31, 2014

Background:

The mission of the U.S. Environmental Protection Agency's (EPA) Office of Water is to protect public health and the environment from adverse effects of pollutants (e.g., toxic chemicals and microbial pathogens) in ambient water, drinking water, wastewater, sewage sludge and sediments. The Safe Drinking Water Act (SDWA) requires the EPA to regulate disease-causing organisms (pathogens) and toxic chemicals in drinking water.

The Safe Drinking Water Act requires the U.S. Environmental Protection Agency (EPA) to publish regulations to control disease-causing organisms (pathogens) and hazardous chemicals in drinking water. One of the regulations published by EPA to control pathogens is known as the Surface Water Treatment Rule (54 FR 27486; June 29, 1989). The Surface Water Treatment Rule seeks to prevent waterborne diseases caused by viruses, *Legionella*, and *Giardia lamblia*. These disease-causing microbes are present at varying concentrations in most surface waters. The rule requires that water systems filter and disinfect water from surface water sources to reduce the occurrence of unsafe levels of these microbes.

The Maximum Contaminant Level (MCL) for *Legionella* is a Treatment Technique. Under U.S. EPA's Surface Water Treatment Rule, systems using surface water or groundwater under the direct influence of surface water must control *Legionella* (U.S. EPA 2002). EPA believes that if *Giardia* and viruses are removed/inactivated according to the treatment techniques in the surface water treatment rules, *Legionella* will also be controlled. EPA has established a Maximum Contaminant Level Goal (MCLG) of zero organisms for drinking water.

Legionella are small gram-negative rod-shaped bacteria. Over 40 individual species of *Legionella* are known. The majority of human infections are caused by the species *Legionella pneumophila*. *Legionella pneumophila* was first discovered following a pneumonia outbreak at the 1976 Convention of the American Legion in Philadelphia. *Legionella* bacteria are found naturally in the environment, usually in water. The bacteria grow best in warm water, like the water found in hot tubs, cooling towers, hot water tanks, large plumbing systems, or parts of the air-conditioning systems of large buildings and large plumbing systems (such as those found in Hospitals). *Legionella* bacteria in water are a health risk if the bacteria are aerosolized (e.g., in an air conditioning system or a shower) and then inhaled. Inhalation can result in a type of pneumonia known as Legionnaires disease or Pontiac fever (both referred to as legionellosis). Legionellosis is a nationally reportable disease and an estimated 8,000 to 18,000 people are hospitalized with Legionnaires' disease each year in the U.S. according to the Centers for Disease Control and Prevention (CDC). Control methods designed to disinfect an entire water distribution system include thermal (super heat and flush) hyper-chlorination copper-silver ionization. Control methods designed to disinfect only a specific portion of a water distribution system include ultraviolet light sterilization, ozonation and instantaneous. Selecting one or a combination of these two types of control methods would be best for eradicating *Legionella* colonies and preventing recolonization of the water distribution system.

The purpose of this document is to serve as an informal technical guidance to assist Federal, state, and local officials responsible for protecting public health when emergency spills or contamination situations occur.

Quality Assurance: Task 2 in this work assignment require the use of secondary data and require a QAPP specific to the activities being conducted. Consistent with the Agency's quality assurance (QA) requirements, the contractor must supplement the quality assurance project plan (QAPP), required under Task 1 of this work assignment, to assure the quality of the secondary data and other data collected to be used under this work assignment. The QAPP must be approved by the EPA WACOR before activities using secondary data begin.

The project specific quality assurance requirements must be addressed in the work plan and monthly progress reports as specified under Task 1 and should follow the attachment titled, QAPP Requirements for projects using secondary data.

Performance Work Statement (PWS):

The work in this PWS will fall under the following tasks:

Task 1: Work plan and monthly progress reports

Task Area 1.1. Work Plan

The contractor shall develop a detail work plan and cost estimate for each task outlined in this work assignment. The plan should contain, but not limited to, work-flowchart, elaborate schedule (task-wise), staffing plan and qualifications of proposed staff, budget for each task and level of effort (LOE). Prior to the submission of the work plan, the contractor shall consult with the EPA WACOR via conference call to mitigate any potential issues that need clarifications. The contractor shall include information on plans to manage work and control contract costs. All P levels, hours and total dollars for each task will be provided and costs greater than \$100.00 shall be itemized in detail. The contractor shall provide their job number with all invoices to facilitate their expediency.

This task also includes monthly progress and financial reports. The monthly progress report shall indicate, in a separate QA section, whether significant QA issues have been identified and how they are being resolved. Monthly financial reports must include a table with the invoice LOE and costs' broken out by the tasks in this WA.

Task Area 1.2. Develop project specific QAPP

Task 2 in this work assignment require the use of secondary data. Consistent with the Agency's quality assurance (QA) requirements, the contractor must comply with the contract level quality assurance project plan (QAPP) dated March 2012 to assure the quality of the secondary data and other data collected to be used under this work assignment. The project specific quality assurance requirements must be addressed in the work plan and monthly progress reports.

The work plan shall explain if any additional QA supplemental information will be submitted based on the specific data requirements of the WA. All projects in Task 2 that involve secondary data must comply with the approved contract level QAPP prior to the commencement of work.

Task 2: Develop Health Assessment document: *Legionella*

2.1 Literature search

In order to develop the document for *Legionella*, a thorough literature search, retrieval, and characterization of the data base on *Legionella* need to be conducted. It is noted that EPA will conduct In-house literature search from 1998 until now and will provide full articles to the contractor through CD or electronically. The literatures prior to 1998 are available at the *Legionella: Human Health Criteria Document* (EPA-822-R-99-001, November 1999, www.epa.gov). The contractor is advised to include those literatures, if needed for the health assessment document.

2.2 Develop analysis plan and conduct exposure and dose response analysis

The health assessment document shall be comprised of a comprehensive review of published literatures on *Legionella* providing all relevant information, the general characteristics of this bacteria, its occurrence in human and animal populations and in

water, drinking water exposures, dose response, the health effects associated with *Legionella* infection are important features of the health assessment and all data of this nature should be captured from both US and foreign data bases. The EPA WAM will provide the *outline for the drinking and ambient water health assessments* to the contractor. The contractor shall evaluate several different permutations of the available feeding study dose response information for various strains and their combination.

The contractor shall coordinate with the EPA WACOR in the collection of datasets for exposure and dose response from various sources for the analysis. Collection of datasets will be conducted such that the Office of Management and Budget (OMB) Information Collection Rule (ICR) will not be triggered.

2.3 Submit draft report of initial findings

The contractor shall prepare a draft *Legionella* health assessment document for the EPA WACOR to review. The contractor shall insure that all factors that were applied to the health assessment are stated and are transparent throughout the document. The contractor shall include a list of references used for this task. In addition, the contractor shall also include a list of unused references along with clear justification for not using them. The contractor shall coordinate with the EPA WAM as inclusion or exclusion of any references to the draft document.

2.4 Incorporate EPA comments and additional studies

The EPA WACOR will periodically search diverse data bases for potential new information and will provide to the contractor. The contractor shall incorporate any additional studies into revisions to draft report upon receipt from EPA WACOR. It is the goal of EPA to gather as many examples as possible and available to help inform the policy development process. The contractor shall also incorporate EPA WACOR review comments to the document.

2.5 Submit revised report

The contractor shall then revise and finalize the health assessment document based upon EPA WACOR review comments.

2.6 Communication piece

The contractor shall provide a brief communication (1- 3 pages) which will aid in briefing manager and senior managers. The communication piece shall be written in plain English language for non-technical people and the relevant scientific studies shall be included as an attachment.

2.7 Response to the Peer Reviewer comments

Upon receipt of the EPA's external expert peer-review of the Contractor's Final Written Report, the EPA WACOR will provide the contractor with the recommended edits and modifications. The contractor shall address all recommended peer-review modifications. Changes will be documented in a separate report for the record to describe how the peer-review comments were incorporated into the final report.

2.8 Incorporate Peer Reviewer comments to the documents

The contractor shall incorporate all recommended edits and modifications to the documents. The contractor shall provide the revised final report (and documented changes to the report) to the EPA WAM WACOR for review.

2.9 Submit Final Report

Upon the EPA WACOR's approval, the contractor shall send the final revised peer-reviewed report in Microsoft Word, version 2003 or higher, to the EPA WACOR.

Period of Performance/Milestones: It is the contractor's responsibility to coordinate with the EPA WACOR while conducting these tasks.

Task	Milestone	Date due
1	1.1 Work Plan	Within 15 days of receipt of WA
1	1.2 QAPP	Within 2 weeks of receipt of WA
1	Kick-off meeting with EPA WAM	Prior to the submission of the WP
2	2.1 EPA will provide literatures and outline for the Health Assessment document	1 week after WP approval
2	2.2 Develop analysis plan and conduct exposure and dose response analysis	3 Weeks after WP approval
2	2.3 Submit draft report of initial findings	1 month after WP approval
2	2.4 Incorporate EPA comments and additional studies, if identified	Six weeks after WP approval
2	2.5 Submit revised report	2 months after WP approval
2	2.6 Communication Piece	TBD
2	2.7 Response to the Peer Reviewer comments	TBD
2	2.8 Incorporate Peer Reviewer comments	TBD
2	2.9 Submit final report	TBD

Knowledge and Skills Required: The contractor shall have expertise in preparing the aforementioned materials and be knowledgeable with the various fields of discipline discussed in this work assignment. The contractor shall be an accomplished microbial risk assessor with experience in environmental media, especially water. The contractor shall have knowledge and experience with the *Legionella* in water and water/wastewater treatment/disinfection effectiveness. The contractor shall be experienced in evaluation of data bases, statistics, and modeling regarding human exposure, dose response and health effects for application in microbial risk assessments.

General Requirements of the Work Assignment and Schedule:

Due Dates: The contractor shall provide due dates that are mutually acceptable with the EPA WACOR. The contractor shall notify the EPA WAM in advance, if a due date will not be met and request a revised date.

Delays: The contractor shall make every effort to ensure there are no contractor-caused delays. If a delay is inevitable, it is the contractor's responsibility to notify the EPA WACOR at the first sign of said delay. A revised schedule will then be worked out.

Draft Documents: The contractor may be required to submit draft documents. Draft documents shall be prepared in an electronic format compatible with current Microsoft products. The EPA WACOR will provide comments on draft submissions prior to submission of final documents.

Final Document: The contractor shall submit final documents both electronically and in hardcopy to EPA WACOR.

Final Document: The contractor shall revise and incorporate all EPA's comments and submit final documents both electronically and in hardcopy (Microsoft version 2003 or higher) to the EPA WAM. The Agency may decide to publish the report on the web. If this occurs, the report will need to be 508 compliant and the EPA WACOR will provide appropriate technical direction.

Final Peer Reviewed Document: Upon receipt of the EPA's external expert peer-review of the Contractor's Final Written Report, the EPA WACOR will provide the contractor with the recommended edits and modifications. The contractor shall address all recommended peer-review modifications. Changes will be documented in a separate report for the record to describe how the peer-review comments were incorporated into the final report. The contractor shall provide the revised final report (and documented changes to the report) to the EPA WACOR for review. Upon the EPA WACOR's approval, the contractor shall send the final revised peer-reviewed report in Microsoft Word, version 2003 or higher, to the EPA WACOR.

Attachment 1

QAPP REQUIREMENTS FOR PROJECTS USING SECONDARY DATA

A secondary data project involves the gathering and/or use of existing environmental data for purposes other than those for which they were originally collected. These secondary data may be obtained from many sources, including literature, industry surveys, compilations from computerized databases and information systems, and computerized or mathematical models of environmental processes. For these projects, a QAPP shall be prepared to include the requirements identified below. If primary data will also be generated as part of the project, then the information below can be incorporated into the associated QAPP to address the secondary data. The following requirements should be addressed as applicable.

SECTION 1.0, PROJECT OBJECTIVES, ORGANIZATION, AND RESPONSIBILITIES

- 1.1 The purpose of study shall be clearly stated.
- 1.2 Project objectives shall be clearly stated.
- 1.3 The secondary data needed to satisfy the project objectives shall be identified. Requirements relating to the type of data, the age of data, geographical representation, temporal representation, and technological representation, as applicable, shall be specified.
- 1.4 The planned approach for evaluating project objectives, including formulas, units, definitions of terms, and statistical analysis, if applicable, shall be included.
- 1.5 Responsibilities of all project participants shall be identified, meaning that key personnel and their organizations shall be identified, along with the designation of responsibilities for planning, coordination, data gathering, data analysis, report preparation, and quality assurance, as applicable.

SECTION 2.0, SOURCES OF SECONDARY DATA

- 2.1 The source(s) of the secondary data must be specified.
- 2.2 The rationale for selecting the source(s) identified shall be discussed.
- 2.3 The sources of the secondary data will be identified in any project deliverable.

SECTION 3.0, QUALITY OF SECONDARY DATA

- 3.1 Quality requirements of the secondary data must be specified. These requirements must be appropriate for their intended use. Accuracy, precision, representativeness, completeness, and comparability need to be addressed, if applicable. (If appropriate, a related QAPP containing this information can be referenced.)
- 3.2 The procedures for determining the quality of the secondary data shall be described.

- 3.3 If no quality requirements exist, this shall be stated in the QAPP. If no quality requirements exist or if the quality of the secondary data will not be evaluated by EPA, the QAPP shall require that a disclaimer be added to any project deliverable to indicate that the quality of the secondary data has not been evaluated by EPA for this specific application. The wording for the disclaimer shall be defined.

SECTION 4.0, DATA REPORTING, DATA REDUCTION, AND DATA VALIDATION

- 4.1 Data reduction procedures specific to the project shall be described, including calculations and equations.
- 4.2 The data validation procedures used to ensure the reporting of accurate project data shall be described.
- 4.3 The expected product document that will be prepared shall be specified (*e.g.*, journal article, final report, *etc.*).

EPAUnited States Environmental Protection Agency
Washington, DC 20460**Work Assignment**

Work Assignment Number

3-13

☐ Other ☐ Amendment Number:

Contract Number

EP-C-11-005

Contract Period 01/01/2011 To 12/31/2014

Base

Option Period Number 3

Title of Work Assignment/SF Site Name

QMRA to Support Water Reuse

Contractor

ICF Incorporated, L.L.C.

Specify Section and paragraph of Contract SOW

3.1, 3.2, 3.3, 3.4, 3.6

Purpose:



Work Assignment



Work Assignment Close-Out



Work Assignment Amendment



Incremental Funding



Work Plan Approval

Period of Performance

From 01/01/2014 To 12/31/2014

Comments:



Superfund

Accounting and Appropriations Data



Non-Superfund

SFO
(Max 2)

Note: To report additional accounting and appropriations data use EPA Form 1900-69A.

Line	DCN (Max 6)	Budget/FY (Max 4)	Appropriation Code (Max 6)	Budget Org/Code (Max 7)	Program Element (Max 9)	Object Class (Max 4)	Amount (Dollars)	(Cents)	Site/Project (Max 8)	Cost Org/Code (Max 7)
1										
2										
3										
4										
5										

Authorized Work Assignment Ceiling

Contract Period:

01/01/2011 To 12/31/2014

Cost/Fee:

LOE:

This Action:

Total:

Work Plan / Cost Estimate Approvals

Contractor WP Dated:

Cost/Fee:

LOE:

Cumulative Approved:

Cost/Fee:

LOE:

Work Assignment Manager Name Sharon Nappier

(Signature)

(Date)

Branch/Mail Code:

Phone Number 202-566-0740

FAX Number:

Project Officer Name Shirley Harrison

(Signature)

(Date)

Branch/Mail Code:

Phone Number: 202-566-1107

FAX Number:

Other Agency Official Name Shirley Harrison

(Signature)

(Date)

Branch/Mail Code:

Phone Number: 202-566-1107

FAX Number:

Contracting Official Name Sandra Stargardt-Licis

(Signature)

(Date)

Branch/Mail Code:

Phone Number: 513-487-2006

FAX Number:

**PERFORMANCE WORK STATEMENT
ICF CONTRACT EP-C-11-005
WORK ASSIGNMENT #3-13**

Title: Quantitative Microbial Risk Assessment (QMRA) to support EPA's potable water reuse efforts

Work Assignment Contracting Officer Representative (WACOR): Sharon Nappier (Mail Code 4304T)
Health and Ecological Criteria Division
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Office of Water, Office of Science and Technology
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Washington, DC 20460
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Alternate WACOR: John Ravenscroft (4304T)
Health and Ecological Criteria Division
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Office of Water, Office of Science and Technology
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Period of Performance: Issuance through December 31, 2014

Contractor SOW: 3.1, 3.2, 3.3, 3.4, 3.6

****Note:** No CBI data will be needed in the course of this work assignment.

Background:

Currently there are no Federal regulations for water reuse. Rather, water reclamation and reuse standards in the United States are the responsibility of state and local agencies. In 1980, EPA developed the first *Guidelines for Water Reuse* as a technical research report for the Office of Research and Development (ORD). There have been several updates to this Guidance, with the most recent being the *2012 Guidelines for Water Reuse*.

Indirect Potable Reuse (IPR) occurs when a utility discharges reclaimed water (treated effluent) to an environmental buffer such as a surface water or groundwater supply and this reclaimed water augments the drinking water supply.

Direct Potable Reuse (DPR), for the purposes of this Performance Work Statement (PWS), means the use of water from a regulated wastewater treatment or recycling facility that is introduced into the drinking water treatment facility without the use of an environmental buffer. DPR *does not* include the introduction of water from a recycling facility *directly* into a drinking water distribution system.

Non-potable Reuse (NPR) is the use of reclaimed water for recreational, agricultural or other uses where direct human ingestion of the water does not occur. Recreational non-potable reuse can include snowmaking. Agricultural non-potable water reuse includes irrigation of food crops intended for human or animal consumption.

Water availability and drought are driving a number of states to examine water reuse as an alternative source of water for potable and non-potable applications. In many states, drinking water utilities are at various stages in considering implementing water reuse. An increasing number of states have been contacting EPA asking for guidance when they are approached by utilities that are contemplating or commencing the process of implementing DPR. A number of states have adopted regulations, guidelines or design standards to cover their water reuse activities. Several states address direct or indirect potable reuse including California, Arizona, New Mexico, Texas, Colorado, Florida, Georgia, Virginia, Wyoming and Washington.

However, there are still scientific gaps relating to potable and non-potable water reuse safety, especially because states are moving forward with different standards and treatment trains and because there is a gap in the knowledgebase for assessing potential human health risks from various routes of exposure to recycled water. For example, many of these safety concerns relate to the risks associated with exposure to chemicals (including mixtures) and microbes in the finished potable water. This work assignment will address human health risks via Quantitative Microbial Risk Assessment (QMRA) from pathogen exposures to various potable and non-potable reuse applications and subsequent exposure routes, including treatment trains currently in use or currently under consideration.

Quality Assurance:

The tasks in this work assignment (WA) require the use of secondary data/analyses and fall under the scope of the approved contract-level QAPP. Consistent with the Agency's quality assurance (QA) requirements, the contractor must assure the quality and analyses of the secondary data and other data collected to be used under this work assignment.

The Contractor shall discuss with the WACOR if any of the specific work assignment tasks are not readily covered under the approved contract-level QAPP. Any additional quality assurance requirements must be addressed in the work plan and monthly progress reports and, if needed, be covered by a WA-specific QAPP supplement, which must be approved by the WACOR before activities covered by the additional QA language begin under this work assignment.

Performance Work Statement: The contractor shall perform the following task areas:

Task 1: Work plan and monthly progress reports

The contractor shall develop a detail work plan and cost estimate for each task outlined in this work assignment. The plan should contain, but not limited to, work-flowchart, elaborate schedule (task-wise), staffing plan and qualifications of proposed staff, budget for each task and level of effort (LOE). Prior to the submission of the work plan, the contractor shall consult with the WACOR via conference call to mitigate any potential issues that need clarifications. The contractor shall include information on plans to manage work and control contract costs. All P levels, hours and total dollars for each task will be provided and costs greater than \$100.00 shall be itemized in detail. The contractor shall provide their job number with all invoices to facilitate their expediency.

This task also includes monthly progress and financial reports. The monthly progress report shall indicate, in a separate QA section, whether significant QA issues have been identified and how they are being resolved. Monthly financial reports must include a table with the invoice LOE and costs' broken out by the tasks in this WA.

Task 1.1 Information Quality Guidelines

The contractor shall ensure the products developed under this work assignment comply with the EPA Information Quality Guidelines and shall complete the Checklist for Influential Information as needed for each deliverable from this work assignment as they may be used in Agency decision-making and/or will be publicly available documents. The WACOR will provide the checklist to the contractor. The contractor shall provide a memorandum describing how the planned product(s) developed meet EPA's Information Quality Guidelines checklist. As part of that memo, the contractor shall document the quality assurance procedures it used in developing the deliverables under this Work Assignment. The contractor shall provide the memo at the time it delivers the Final Summary Report. As requested by the WACOR, the contractor shall have a teleconference with the WACOR to discuss the Guidelines and the contractor's role in completing the checklist.

TASK 2 – Quantitative Microbial Risk Assessment of Water Reuse Scenarios

The contractor shall develop QMRAs to support HECD efforts to estimate human health risks from various exposure routes and water reuse scenarios. The scenarios may range from indirect to direct reuse applications. The contractor shall develop appropriate planning and scoping activities prior to conducting risk analyses. Planning and scoping activities will include the delineation of the important risk management questions and potential science gaps that the assessment could address. Additionally, these activities shall include the identification of the exposure routes of interest, relevant pathogens

and pathogen indicators, etc. The contractor shall also develop a problem formulation, including a data inventory, for any reuse scenario that is modeled. The contractor shall develop a risk characterization for each QMRA conducted under this task that discusses the interpretation of the risk modeling and analyses. This interpretation shall be a synthesis exercise and include sensitivity and uncertainty analysis and interpretation. The contractor shall frame the risk characterization to reflect the problem formulation such that it is useful for informing decision-making at EPA. The contractor shall coordinate these activities with the WACOR and other technical staff.

Task 2.1 *Distributions of Pathogens and pathogen indicators*

As part of this project, the contractor shall build on the viral distribution work completed under WA 3-08. The contractor shall create, as specified by the WACOR, distributions of pathogenic protozoa, bacteria, and viruses in raw sewage, and in wastewater that has undergone various stages of treatment or retention time in environmental matrices. Viruses can include norovirus, adenovirus, rotavirus, etc. Protozoans can include, but are not limited to, *Giardia spp.* and *Cryptosporidium spp.* Bacteria can include, but are not limited to, *Legionella spp.*, *Mycobacterium Avium* Complex (MAC), *E. coli* O157:H7, *Campylobacter spp.*, etc. Additionally, the contractor may also be required to develop distributions of pathogen indicators as needed and specified by the WACOR.

Task 2.2 *QMRA of Multiple Treatment Trains*

Using the pathogen distribution information developed under task 2.1, the contractor shall conduct a QMRA for estimating human health risks from exposure to waters that have undergone multiple treatment trains and are intended for use under a DPR scenario. Multiple treatment trains, such as Full Advanced Treatment (FAT), will be explored. Additionally, multiple disinfectant regimes may be explored.

Task 2.3 *Other QMRAs*

As directed by the WACOR, the contractor shall conduct a QMRA for other exposure and water reuse scenarios as needed to help inform decision making in EPA's Office of Water.

Task 2.4 *EPA Reports and Peer-review Publications*

The contractor shall submit the QMRA work as both an EPA report for internal review and as a peer-review publication manuscript. EPA anticipates there will be several internal reviews of both the EPA report and manuscript prior to publication. The contractor shall assist in incorporating comments and edits and deliver final products. Manuscripts shall be prepared once the submitted report is of sufficient quality for publication. At EPA's direction, the contractor shall make the final EPA document 508

compliant.

Travel: Local travel is anticipated for this task. No contractor travel outside of the Washington, D.C. metro area is required.

Task Area 3 - General Project Support

The contractor shall, based on technical direction given by the WACOR, provide support in conducting literature searches of the peer reviewed scientific literature and in preparing interim project updates and other materials for internal and external audiences. Literature searches will aid the development of the QMRAs conducted under Task 2. Updates and other support materials may include, but are not limited to, short briefing documents, white papers and PowerPoint presentations. The contractors may also be directed to participate in and/or conduct briefings. A weekly update call with the WACOR will be required for this work assignment, as needed.

Some meetings may require contractor support and/or attendance for note-taking, presentations, and meeting preparation materials. Details on travel dates and locations will be provided by the WACOR through technical direction, as further information becomes available.

Travel: Travel may be needed as deemed necessary by the WACOR. No contractor travel outside of the Washington, D.C. metro area is required.

Knowledge and Skills Required: The contractor shall have expertise in preparing the aforementioned materials and be knowledgeable with the various fields of discipline discussed in this work assignment. The contractor shall have practical experience in conducting microbial risk assessments and have advanced credentials in environmental microbiology. The contractor shall be familiar with viral, protozoan, and bacterial indicators and pathogens, microbiological analytical methods (including molecular techniques), biostatistics, quantitative microbial risk assessment, environmental engineering, and direct and indirect potable water reuse. The contractor shall be familiar with the interpretation of indicator and pathogen monitoring results and how those results are related to risk estimates and public health protection.

General Requirements of the Work Assignment and Schedule:

Due Dates: The contractor shall provide due dates that are mutually acceptable with the WACOR. The contractor shall notify the WACOR in advance, if a due date will not be met and request a revised date.

Delays: The contractor shall make every effort to ensure there are no contractor-caused delays. If a delay is inevitable, it is the contractor's responsibility to notify the WACOR at the first sign of said delay. A revised schedule will then be worked out.

Draft Documents: The contractor may be required to submit draft documents. Draft documents shall be prepared in an electronic format compatible with current Microsoft products. The WACOR will provide comments on draft submissions prior to submission of final documents.

Final Documents: The contractor shall submit final documents both electronically and in hardcopy to WACOR.

Milestone/Deliverable Table

Task	Task #	Milestones and Due Dates
Task 1: Work plan, monthly progress reports and quality assurance		
Workplan	1	Within 15 calendar days after receipt of work assignment
Information Quality Guidelines	1.2	Discuss with WACOR within 15 calendar days after receipt of work assignment. IQG checklists due with final deliverable (can be included with QA materials).
Task 2: Quantitative Microbial Risk Assessment		Initial planning meeting to be held within 15 calendar days after receipt of work assignment. Subsequent meetings to be held roughly weekly, as needed, for each QMRA that is conducted; the contractor shall meet with the WACOR to discuss planning and scoping and develop the problem formulation.
Distributions of Pathogens and pathogen indicators	2.1	After the workplan approval, throughout the period of performance. Initial planning meeting with WACOR and other technical staff within 15 calendar days of Work Plan approval or as specified by the WACOR.
QMRA of Multiple Treatment Trains	2.2	TBD
Other QMRAs	2.3	TBD
EPA Reports and Peer-review Publications	2.4	Unless specified by the WACOR, the schedule for report and manuscript deliverables is as follows (please note that not all draft deliverable milestones will apply to all deliverables):

		<p>Reports: Draft for WACOR review – 2 weeks after receiving WACOR comments; Draft for peer review – 1 week after receiving WACOR comments; Final for WACOR review – 2 weeks after receiving peer review comments; Final for publication – 2 weeks after receiving WACOR comments.</p> <p>Manuscripts: Draft for WACOR review – 2 weeks after receiving WACOR comments; Final – 1 week after receiving WACOR comments and approval.</p>
Task 3: General Project Support		TBD

Attachment 1

QAPP REQUIREMENTS FOR PROJECTS USING SECONDARY DATA

A secondary data project involves the gathering and/or use of existing environmental data for purposes other than those for which they were originally collected. These secondary data may be obtained from many sources, including literature, industry surveys, compilations from computerized databases and information systems, and computerized or mathematical models of environmental processes. For these projects, a QAPP shall be prepared to include the requirements identified below. If primary data will also be generated as part of the project, then the information below can be incorporated into the associated QAPP to address the secondary data. The following requirements should be addressed as applicable.

SECTION 1.0, PROJECT OBJECTIVES, ORGANIZATION, AND RESPONSIBILITIES

- 1.1 The purpose of study shall be clearly stated.
- 1.2 Project objectives shall be clearly stated.
- 1.3 The secondary data needed to satisfy the project objectives shall be identified. Requirements relating to the type of data, the age of data, geographical representation, temporal representation, and technological representation, as applicable, shall be specified.
- 1.4 The planned approach for evaluating project objectives, including formulas, units, definitions of terms, ~~statistical~~ data analysis (i.e. statistical analysis & any other types of data analysis), and assumptions/recommendations based on the data analysis, if applicable, shall be included.
- 1.5 Responsibilities of all project participants shall be identified, meaning that key personnel and their organizations shall be identified, along with the designation of responsibilities for planning, coordination, data gathering, data analysis, report preparation, and quality assurance, as applicable.

SECTION 2.0, SOURCES OF SECONDARY DATA

- 2.1 The source(s) of the secondary data must be specified.
- 2.2 The rationale for selecting the source(s) identified shall be discussed.
- 2.3 The sources of the secondary data will be identified in any project deliverable.

SECTION 3.0, QUALITY OF SECONDARY DATA

- 3.1 Quality requirements of the secondary data must be specified. These requirements must be appropriate for their intended use. Accuracy, precision, representativeness, completeness, and comparability need to be addressed, if applicable. (If appropriate, a related QAPP containing this information can be referenced.)
- 3.2 The procedures for determining the quality of the secondary data shall be described.
- 3.3 If no quality requirements exist, this shall be stated in the QAPP. If no quality requirements exist or if the quality of the secondary data will not be evaluated by EPA, the QAPP shall require that a disclaimer be added to any project deliverable to indicate that the quality of the secondary data has not been evaluated by EPA for this specific application. The wording for the disclaimer shall be defined.

SECTION 4.0, DATA REPORTING, DATA REDUCTION, AND DATA VALIDATION

- 4.1 Data reduction procedures specific to the project shall be described, including calculations and equations.
- 4.2 The data validation procedures used to ensure the reporting of accurate project data shall be described.
- 4.3 The expected product document that will be prepared shall be specified (*e.g.*, journal article, final report, *etc.*).